



Futura Medical plc  
Annual Report and  
Accounts 2020

# Welcome to the Futura Medical Annual Report

## WHAT WE DO

Futura Medical is a pharmaceutical company developing a portfolio of innovative products based on our proprietary, transdermal technology DermaSys®.

These products are optimised for clinical efficacy, safety, mode of administration and patient convenience and are developed for the prescription and consumer healthcare markets as appropriate.

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

“Our purpose is to enhance our patients and consumers’ quality of life to enable them to live their lives to the full.”

**JAMES BARDER**  
Chief Executive





## INVESTMENT CASE

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.

### 1.

#### Short and long-term value creation from our lead product MED3000

We are prioritising the development and regulatory approval for MED3000, our treatment for erectile dysfunction, owing to its significant short and 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 all co-primary clinical endpoints against baseline (before treatment). We recently received the recommendation by the EU Notified Body for the approval of MED3000 in the EU as a medical device without the need of a doctor's prescription and are commencing a small confirmatory Phase 3 clinical trial in preparation for a regulatory filing in the US.

### 3.

#### 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.

### 5.

#### Strategic relationships and partnerships

As a semi-virtual company we value our partners and place much emphasis on selecting partners who are experts in their field and highly motivated, whether this is for running our clinical trials, manufacturing our clinical supplies and commercial stock or indeed for the critical role of commercialising our products. We look for committed commercial partners who have the regulatory and commercial expertise as well as the drive and enthusiasm to make our products a success.

### 2.

#### Advanced proprietary technology DermaSys®

We are exploiting the potential of our transdermal technology DermaSys® to innovate and develop topical treatments offering a fast onset of action and low systemic side effects. Our long-term strategy is to expand the product pipeline based on DermaSys®. We are currently exploring opportunities with cannabidiol in CBD100. Our products are underpinned by strong IP, usually specific to each product.

### 4.

#### De-risked strategy which focuses on rapid routes to market

We have a late stage pipeline of products, developed from well characterised molecules and excipients with an established safety profile. This means that there is a lower development risk and potentially shorter regulatory pathway.

### 6.

#### Experienced management team

The management team has significant experience in researching and developing innovative products for the global consumer healthcare and prescription markets, with extensive development and regulatory expertise in the US and Europe.

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## HIGHLIGHTS

# Remarkable regulatory progress with MED3000 during Financial Year 2020 and into 2021

## OPERATIONAL HIGHLIGHTS

### MED3000 – TOPICAL FAST-ACTING TREATMENT FOR ERECTILE DYSFUNCTION (“ED”)

- Significant progress made with recent recommendation by EU Notified Body<sup>1</sup> for the approval of MED3000 as a breakthrough, fast-acting, clinically proven treatment for erectile dysfunction:
  - In February 2020 formal proceedings commenced for approval as a medical device available throughout the EU without the need of a doctor’s prescription (“OTC”).
  - In July 2020, Futura submitted the Technical Dossier for MED3000 for marketing approval.
  - In August 2020 positive audit opinion received for Futura’s Quality Management Systems (“QMS”).
  - EU certificate expected before the end of May 2021 under Medical Device Regulation.
- De Novo medical device status for MED3000 confirmed by US Food and Drug Administration (“FDA”) in February 2020 pre-submission meeting.
  - Four pre-submission meetings held to determine design of small supplemental clinical trial (known as “FM71”) and Human Factors study required by FDA for OTC marketing approval in US.
  - Planning and preparatory activities for FM71 have commenced following receipt of final minutes from the FDA in March 2021.

- Specialist corporate advisers retained in July 2020 to progress commercialisation of MED3000:
  - Joint collaboration agreement for China and South East Asia with 50/50 share of profits signed in March 2021 with expected additional R&D costs of up to £4 million being fully met by Asian partner.
  - Discussions are progressing with a number of other parties for licensing rights for MED3000 in other countries.

### CBD100 – FUTURA’S ADVANCED PROPRIETARY TRANSDERMAL TECHNOLOGY, DERMASYS® FOR TRANSDERMAL DELIVERY OF CANNABIDIOL

- Initial laboratory and optimisation work on a cannabidiol gel under the joint venture collaboration agreement with CBDerma Technology Limited completed in August 2020.
- In vitro studies supported a stable formulation with enhanced permeation through the skin of cannabidiol.
- An intellectual property application filed in August 2020 covering a novel and inventive formulation with recent progression to PCT<sup>2</sup> patent application.
- Advisers recently retained to explore commercial opportunities.

### TPR100 – FUTURA’S ADVANCED PROPRIETARY TRANSDERMAL TECHNOLOGY, DERMASYS® FOR TRANSDERMAL DELIVERY OF DICLOFENAC FOR THE PAIN AND INFLAMMATION ASSOCIATED WITH SPRAINS, STRAINS, BRUISES AND SOFT TISSUE RHEUMATISM

- Completion of additional laboratory work required by the UK Medicines and Healthcare Products Regulatory Agency (“MHRA”) to support the UK submission made by partner Thornton & Ross supporting improved skin permeation of TPR100 compared to market leading products.
- Scientific advisory meeting held with MHRA confirming the need of a Phase 3 study to support the improved skin permeation and potential potency of TPR100 including potential superior efficacy claims.
- Futura is exploring the feasibility of a clinical study that would satisfy the Phase 3 requirements for both UK and US marketing approval.

1. Notified Bodies are organisations designated by EU countries to oversee the approval of medical devices within the EU and the UK.

2. Patent Cooperation Treaty



## FINANCIAL HIGHLIGHTS

- £2.41 million net loss in the period (2019: net loss £8.92 million).
- R&D tax credit receipt for 2020 year of £0.52 million expected mid-2021.
- Cash resources of £1.02 million at 31 December 2020 (2019: £2.51 million).

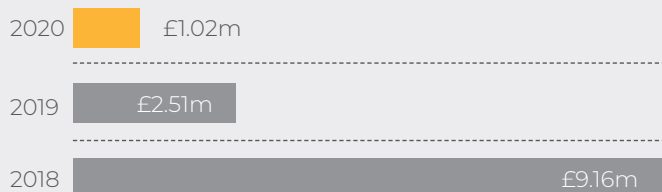
### POST PERIOD FINANCING

- Futura received £1.50 million through the issuance of convertible loan notes to Atlantis via HT Riverwood Fund, with a three year conversion period at a premium price of 20 pence.
- Futura also received £0.50 million following the exercise of warrants by Atlantis via HT Riverwood Fund, issuing 2,272,727 shares at an exercise price of 22 pence per warrant.



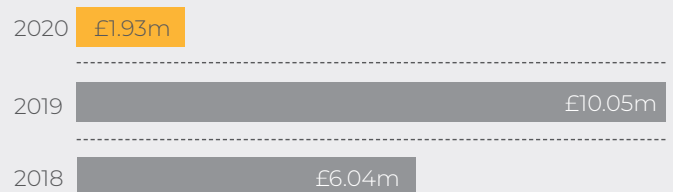
### CASH BALANCE

£1.02m  -59%



### R&D SPEND

£1.93m  -81%



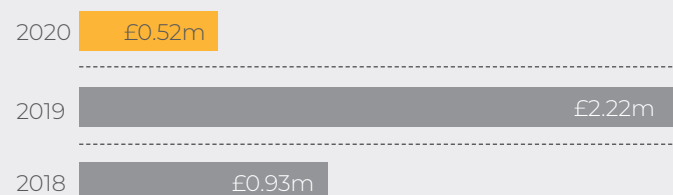
### OPERATING LOSS

£2.93m  -74%



### R&D TAX CREDIT

£0.52m  -77%



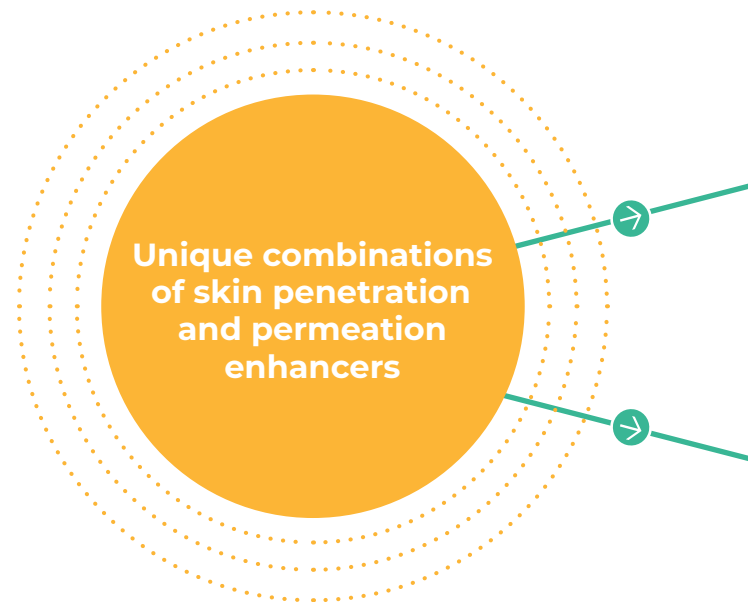
## DERMASYS® AT A GLANCE

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

### APPLYING SKIN SCIENCE TO DELIVER NOVEL TOPICAL TREATMENTS

Our core strength lies in our research and development capabilities in the field of topical formulations and transdermal delivery. Futura's unique technology, expertise and know how, enables targeted and rapid delivery of active pharmaceutical ingredients (API) and Generally Recognized As Safe (GRAS) pharmaceutical excipients onto and through the skin to the required site of action with a high level of safety. We take off-patent, generic molecules and excipients 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.

### At the core of DermaSys®



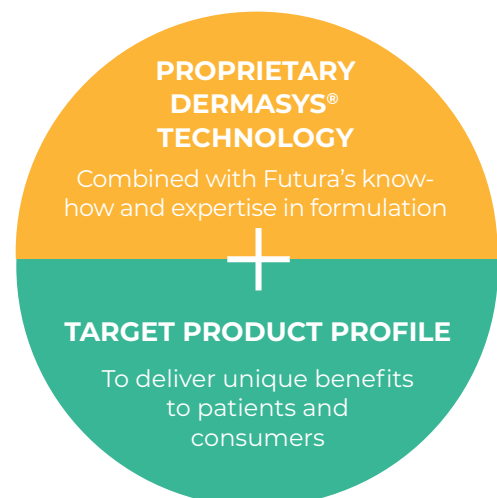
### DERMASYS® AND THE PROCESS BEHIND OUR UNIQUE FORMULATIONS

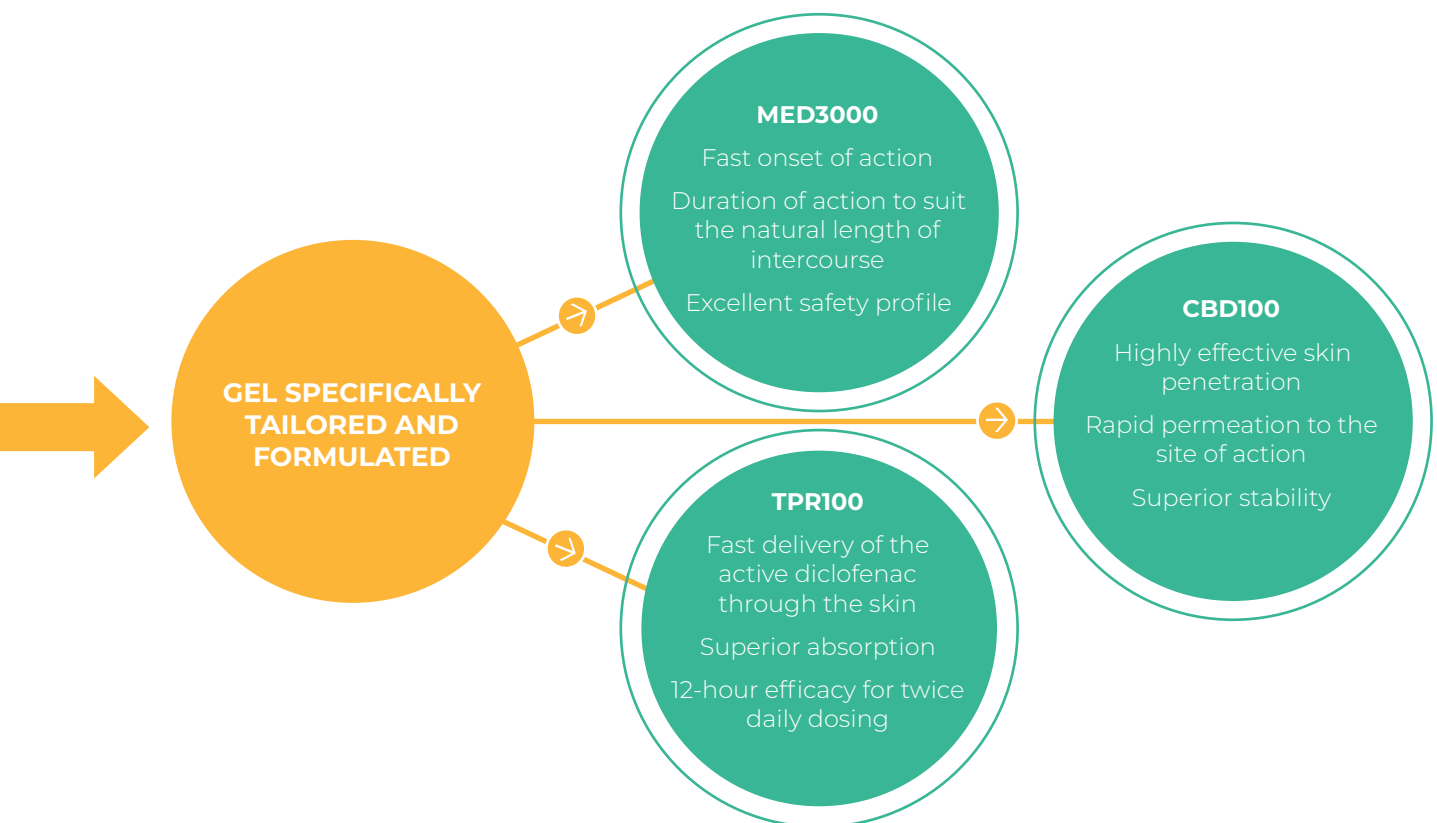
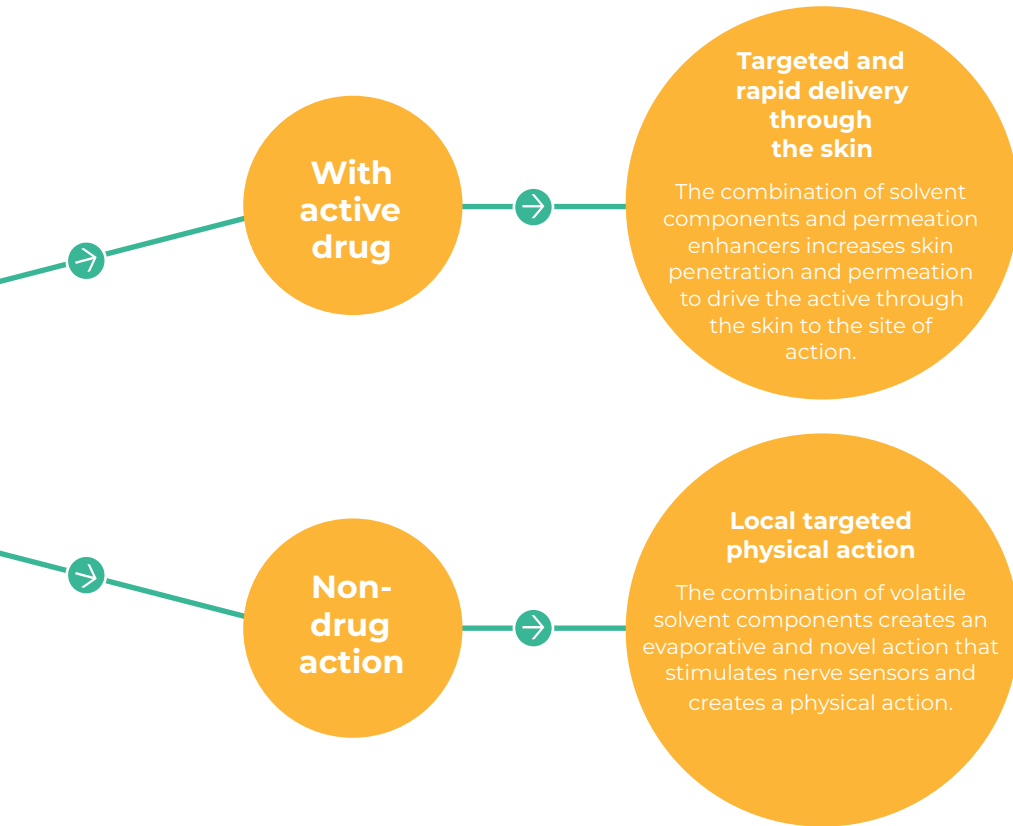
Our unique patented technology DermaSys® is designed to deliver clinically proven effective medical treatments via the skin.

DermaSys® is a versatile and bespoke technology. Each gel is uniquely formulated using the DermaSys® platform with penetration and permeation enhancer components tailored for each product to suit the specific therapeutic indication 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 odourless and provide effective and local topical application to the required site of action. For our erectile dysfunction treatment, MED3000, this translates into a fast-acting treatment for erectile dysfunction with an excellent safety profile. For our pain relief treatments, TPR100 and TIB200, this translates into effective penetration for enhanced therapeutic benefits with fast, effective and long-lasting relief.

### DermaSys® process







# OUR BUSINESS MODEL

## KEY RESOURCES

### 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

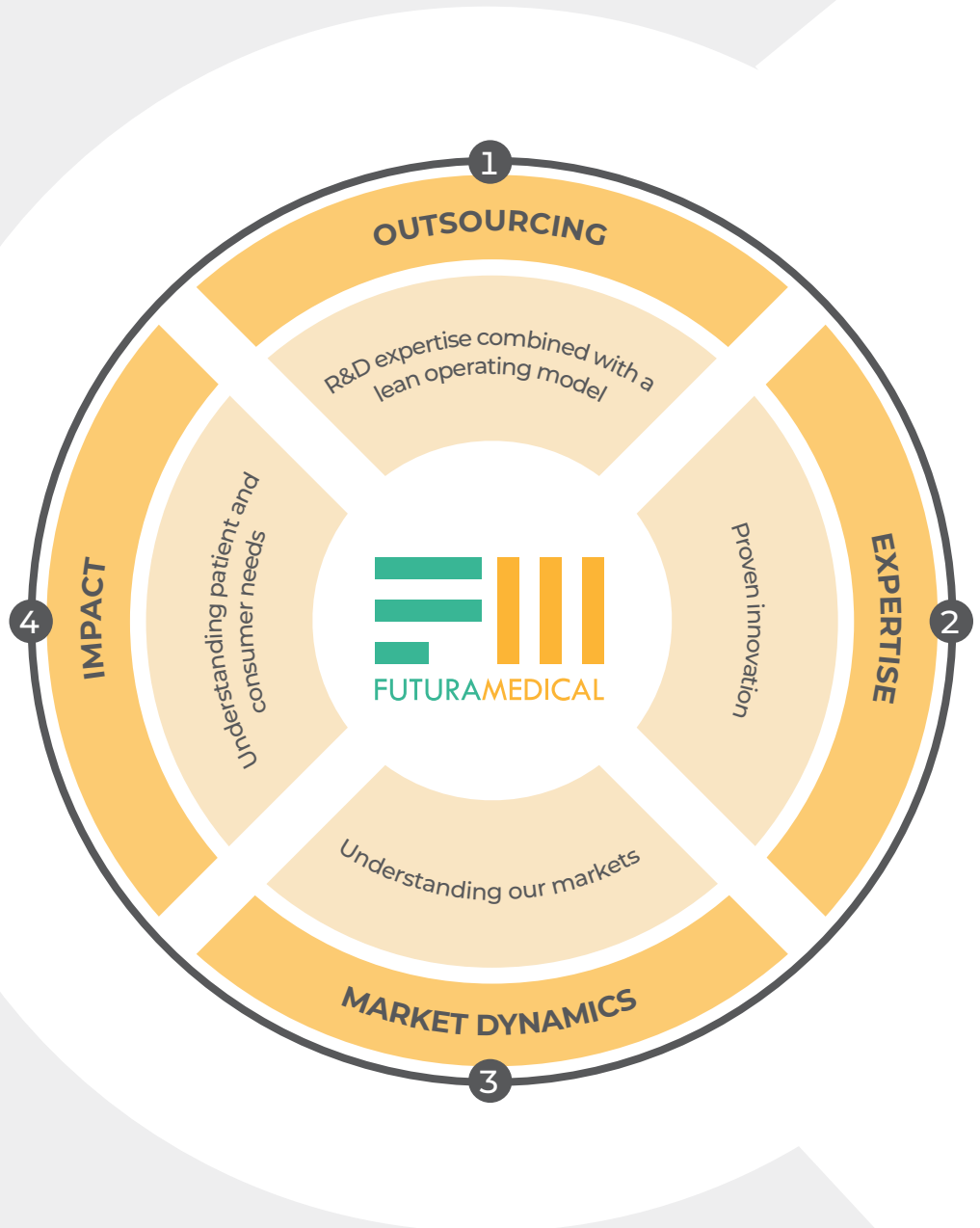
- Highly efficient patented proprietary transdermal technology
- Semi-virtual structure with outsourcing optimised to maximise expertise and minimise overhead cost

### STRONG LEADERSHIP

- Experienced management team with background in researching and developing innovative products for global consumer healthcare and prescription markets

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

## HOW WE CREATE VALUE



## 1 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) to lead strategy and co-ordinate the outsourcing of key activities with a range of experienced consultants and highly regarded subcontractors.

## 2 EXPERTISE – PROVEN INNOVATION

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

## 3 MARKET DYNAMICS – UNDERSTANDING OUR MARKETS

Our lead asset MED3000, as well as the rest of our pipeline assets, are 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 of life, lead to increased demand. Not only are people living longer but they want to live an active, pain-free and fulfilled lifestyle for longer. Products such as MED3000 are well placed to accommodate such demands.

## 4 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 self-esteem and have a significant impact on male mental health.

## MAXIMISING VALUE

We continue to execute our R&D strategy whilst evaluating our options to maximise value from future commercialisation of our lead assets with potential commercial partners.

### COMMERCIALISING OUR PRODUCTS

As we expect the EU CE mark certificate before the end of May for MED3000 as a medical device and are progressing through to regulatory approval in the US, we are focusing our efforts on finding the best commercial partners. We look for committed commercial partners who have the regulatory and commercial expertise in their markets as well as the drive and enthusiasm to make our products a success.

## CREATING VALUE FOR OUR KEY STAKEHOLDERS

### PATIENTS

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 live 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 the value that Futura retains from our US\$1 billion<sup>1</sup> sales potential erectile dysfunction product. This is to be achieved by gaining regulatory approval as an effective clinically proven treatment for erectile dysfunction.

Read more information on our stakeholders on pages 40 and 41.

1. Previous market research conducted by Cello Health Consulting as a prescription product and Ipsos Group as an over-the-counter product on MED2005 showed potential peak sales in excess of US\$1 billion. 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.

## PRODUCTS AND PIPELINE

Futura Medical is developing a portfolio of innovative products for two large markets, sexual health and pain. We have four products in late-stage development, with MED3000 and TPR100 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 6% in 1990 to 9% in 2019<sup>1</sup>. Age is a main factor for the incidence of erectile dysfunction as well as local pain.

#### INCREASING PROSPERITY

As of 2016, 3.2 billion people globally are considered middle class. A study by the Brookings Institution estimates this number to increase by 140 million annually. In developed countries people in their older years have less financial commitments and therefore more disposable income.

#### INCREASED QUALITY OF LIFE

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

#### INCREASING OVERALL PATIENT DEMAND

With more disposable income and higher expectations from consumers and patients towards their sexual health and the desire to lead a full and active lifestyle, our expectation is 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 which has Phase 3 clinical data demonstrating highly statistically significant improvement across all ED patient severities with potential peak sales of US\$1 billion<sup>2</sup>.



#### PAIN RELIEF

Pain relief gels TPR100 and TIB200 offer targeted and long-lasting pain relief and have the potential for improved patient benefit by offering a fast, highly effective and long-lasting (12 hr) relief. CBD100, which is an optimised cannabidiol formulation, is in development for potential use in a variety of conditions including pain, though initially it will likely be marketed as a cosmeceutical.



1. World Population Ageing 2019 report, United Nations.
2. Previous market research conducted by Cello Health Consulting as a prescription product and Ipsos Group as an over-the-counter product on MED2005 showed potential peak sales in excess of US\$1 billion. 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 PRODUCT PIPELINE

### Commercial stage

<b>MED3000</b>	<b>Topical treatment for erectile dysfunction</b>	<p>MED3000 recommended by the EU Notified Body for approval in the EU as a medical device. Clear regulatory pathway as a medical device in the US with FDA endorsement of Phase 3 clinical study protocol FM71. First deal signed for China and South East Asia with discussions ongoing for the licensing rights in other territories as part of an agreed process managed by Futura's advisers.</p> 
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### Development stage

<b>TPR100</b>	<b>Topical diclofenac pain relief gel</b>	<p>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.</p> 
<b>CBD100</b>	<b>Topical cannabidiol formulation</b>	<p>Joint venture collaboration. Early development stage completed. IP application filed. Advisers recently retained to explore commercial opportunities.</p> 
<b>TIB200</b>	<b>Topical ibuprofen pain relief gel</b>	<p>Partnering discussions ongoing.</p> 



## CHAIRMAN AND CHIEF EXECUTIVE'S REVIEW

# A transformational year for Futura with MED3000's value rapidly crystallising

## COVID-19 UPDATE

Futura Medical continues to monitor closely the constantly evolving situation in relation to the coronavirus outbreak and all necessary steps have been 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 semi-virtual business and we have been able to transition quickly to a fully remote and flexible working model with ease.

We are currently not conducting any trials requiring the use of patients or healthy volunteers. We continue to monitor ongoing developments as we prepare to conduct clinical study FM71 in support of MED3000's regulatory filing in the US. All other operational activities can be managed using existing internal resource and our extensive resource of external consultants and subcontractors should any of our employees become ill. We continue to expect limited impact from COVID-19 during 2021.

Futura is an innovative R&D company with a strategy to develop a pipeline of late stage, novel products borne out of its proprietary patented transdermal technology platform, DermaSys®. The Company is currently focused on sexual health and pain. It seeks to develop products with high tolerability, safety and convenience of administration that solve clinically meaningful problems, including dissatisfaction with existing treatments, to improve health, quality of life and well-being for patients worldwide. Whilst we apply strict pharmaceutical principles and discipline to both the R&D and manufacturing process to all our product candidates, we also aim to ease access to our treatments for patients, for example through the registration and ultimately availability as over-the-counter ("OTC"), non-prescription, products.

This year against the backdrop of the turbulence and challenges posed by the COVID-19 pandemic across the world, the team at Futura has been resolutely focused on execution, particularly the regulatory submission for MED3000 in Europe (completed H2 2020) and the US (an ongoing iterative consultation and review process), as well as advancing activities for its commercialisation. At the same time, we also progressed additional pipeline product candidates, such as our CBD100 cannabidiol formulation, that will address attractive and substantial markets.

These efforts are now starting to bear fruit, most recently culminating in the March 2021 recommendation for approval of MED3000 from the EU Notified Body, a transformational milestone for us. Once its Medical Device Regulation certificate as a Class 2B approved medical device is received and CE mark is granted, expected before the end of May 2021, Futura's breakthrough, fast-acting topical gel formulation MED3000, will become the first clinically proven, pan-European OTC topical treatment for erectile dysfunction ("ED") available without a doctor's prescription.

Due to post-Brexit arrangements, the EU CE mark can be used to market the product in Great Britain<sup>1</sup> until 30 June 2023, by which time a specific UKCA mark has to be obtained. This will be a streamlined process since it is understood the UK application can bridge to the EU approval.

We look forward to further MED3000 marketing approvals in multiple regions across the world, including the US and Asia. Expedited Medical Device Registrations may be possible in most Middle East, Far East, African and Latin American countries based on the EU CE mark and we will be targeting both further regulatory approvals as well as commercial launch in a number of countries.

Futura retained specialised corporate advisers in Q3 2020 to facilitate active commercial discussions for MED3000 with potential licensing and marketing partners. In early March 2021 we announced a joint collaboration and investment to commercialise MED3000 in China

**JOHN CLARKE**

Chairman

**JAMES BARDER**

Chief Executive



and South East Asia, a significant market for ED. Our new partners have extensive experience, resource, and strong pharmaceutical connections in the Asia Region which we are confident will maximise the market reach and opportunities for MED3000 in those geographies, creating significant long-term value. Key components of this partnership mean that Futura shares 50% of MED3000 profits from the Region without further R&D spend (from Futura). In addition, the Company has received £2 million cash from partner investment in Futura. This partnership is an example of Futura's strategy to maximise value creation by partnering or out-licensing its products at key inflection points with agreements that look to capture long-term and sustainable returns for the Company.

As a small innovative company Futura is adaptable and nimble, allowing us to take advantage of new opportunities and strategies as those opportunities arise as well as evolve to meet challenges. We would like to thank all Futura's employees for their tremendous efforts and focus during the year and shareholders for their ongoing support. We have been able to leverage the lean, semi-virtual working processes at Futura to adapt to the pandemic efficiently and safely, whilst making significant progress for our products. Post-pandemic, Futura will be adopting a partly remote working model moving forward.

MED3000 will be the first clinically proven, pan-European OTC topical treatment for erectile dysfunction available without a doctor's prescription.

**OPERATIONAL REVIEW****DermaSys® – 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 partition and diffusion 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.

**A transformational year with EU recommendation for approval of MED3000 - Topical gel for erectile dysfunction ("ED")**

MED3000 is a formulation of the proprietary technology DermaSys®, developed specifically for the treatment of ED. Data from a Phase 3 clinical study "FM57" has supported the regulatory submission for MED3000 as a medical device in Europe with clinically proven claims for the treatment of ED. The studies have demonstrated that MED3000 has the potential to be a highly differentiated product by addressing significant unmet needs, across all patient severities in the US\$5.6 billion ED market<sup>2</sup>, thanks to its rapid 10 minute speed of onset enabling spontaneity for both partners, significant clinical benefits alongside low side effects and no interactions with alcohol or food, as well as providing a potential treatment option for around 20% of ED<sup>3</sup> patients contraindicated from using existing ED therapies. Futura also believes MED3000 data approaches the efficacy of current first line therapy



## CHAIRMAN AND CHIEF EXECUTIVE'S REVIEW

but with significantly lower adverse events and will be of high interest to the medical community for those patients who are seeking a treatment that provides them and their partners spontaneity through MED3000's very rapid onset of action along with a very low side-effect profile. Its excellent safety profile makes it ideally suited to become a unique topical formulation available without a doctor's prescription.

ED disrupts the lives of at least one in five men globally<sup>4</sup>, affecting the sexual and emotional health of around 23 million men and their partners in the US, and 20 million men in the UK, France, Italy and Germany alone. The prevalence of ED amongst adult males<sup>5</sup> is estimated to be 340 million in the key markets, with China ranked first and US ranked fourth. Of note, the prevalence of ED in young men is increasing; now as high as 30%<sup>6</sup>. There has been little innovation in ED treatments for over ten years and many patients continue to suffer dissatisfaction with existing treatments, a statement frequently made by Key Opinion Leaders in the field of sexual medicine.

### FM57 study

FM57, the Phase 3 study conducted with MED3000 was a 1,000-patient study including approximately 60 centres across nine Central and Eastern European countries. FM57 was a dose ranging, randomised, double blind, home use, parallel group clinical trial. Patients being enrolled into FM57 for the initial four weeks had to attempt intercourse on at least four occasions to establish the severity of their ED, known as the pre-treatment "baseline".

### FM57 results – MED3000 shown to be an extremely effective treatment for ED with an excellent safety profile

In study FM57 all three co-primary endpoints (IIEF-EF, SEP2 and SEP3; internationally accepted clinical trial

endpoints in ED) were statistically significantly achieved against baseline (pre-treatment) data in addition to important, supporting secondary endpoints in terms of efficacy, speed of onset, duration of action and clinically meaningful differences in patient benefit.

FM57 demonstrated that MED3000 has the potential to be a highly effective, clinically proven, topical treatment for ED. MED3000 has a unique evaporative mode of action which the Company believes stimulates nerve endings in the glans penis to cause an erection.

MED3000 results demonstrated a highly statistically significant improvement ( $p < 0.001$ ) in erectile function across "pooled" patient severities (mild, moderate, and severe) as well as being statistically significantly superior within the separate mild, moderate and severe patient groups, compared to before treatment baseline, along with an excellent safety profile.

Importantly, MED3000 had a significant clinically meaningful effect in 60% of patients as calculated using the Rosen and Araujo statistical method, a standard assessment technique for measuring Patient Reported Outcomes recognised and accepted by leading ED experts. Such Patient Reported Outcomes in ED are key evaluation criteria for regulators as well as physicians and their patients. 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 PDE5i's (oral tablets) with significant benefits for spontaneous rather than pre-planned sexual intercourse.

Overall, the level of efficacy was broadly equivalent to lower doses of current oral ED treatments. Safety and tolerability data were also highly positive, with no serious adverse events recorded in any patient, or their female partners.

### MED3000 – Medical device regulatory pathway

During 2020 the Company navigated the complex formal regulatory proceedings for MED3000 in both Europe and the US. Regulatory procedures, timelines and approaches differ by region.

**Europe:** In March 2021, Futura announced that the EU Notified Body had successfully completed its review of the Company's Technical Dossier for MED3000 with a recommendation to approve MED3000 for the medical device class and indication as applied for in July 2020. A Class 2B approval is by definition an approval allowing marketing of MED3000 as a non-prescription treatment across the European Union. European approval for MED3000 will be final upon issuance of a Medical Device Regulation certificate by the panel, which is expected before the end of May 2021.

In order to obtain pre-marketing clearance within the EU under the new Medical Device Regulations, two requirements have to be met: Submission of Technical Documentation which includes sufficient efficacy, safety and quality data; and demonstration that the Company can operate to a high standard of quality through a Quality Management System ("QMS").

In July 2020, Futura submitted the Technical Dossier for MED3000 for the treatment of ED under the European Medical Device Regulation for marketing approval in Europe by an EU Notified Body as a Class 2B medical device. The Technical Dossier included data in support of quality, safety and efficacy of MED3000.

Once EU certification and the resultant CE mark is granted, MED3000 will become the first pan-European topical OTC treatment for ED. This paves the way for approval in many countries around the world, including in the Middle East, Africa, the Far East and Latin American regions which allow “fast-track” review based on recognition of the EU CE mark. The CE mark will also be recognised in Great Britain until 30 June 2023 and in the period leading up to this Futura will secure the new post-Brexit UKCA mark. This will be a streamlined process since it is understood the UK application can bridge to the EU approval.

**US:** FDA’s guidance documents indicate that their preference is to adopt an interactive and iterative approach to data requirements through pre-submission meetings with sponsors. According to FDA, careful considerations of their feedback may improve the quality of subsequent submissions, shorten total review times and facilitate the development process for new devices. Thus, our productive and positive pre-submission meetings were held during 2020 and early 2021 to discuss existing FM57 Phase 3 clinical data, pathway to OTC status and any additional clinical and non-clinical requirements.

Summarising activity to date: it has been established that an application may be made for MED3000 as a medical device for ED treatment, with a De Novo Classification. FDA requires an additional six month confirmatory clinical study, known as “FM71”, with MED3000 taking a “least burdensome approach” with detailed design now agreed. A short, non-clinical, Human Factors Study, testing ease of patient understanding of an OTC label and product administration and use is also requested to support the regulatory submission and facilitate OTC status as well as a finalised OTC product label.



A fifth pre-submission meeting with FDA is planned for H2 2021 to define and confirm the detail of the work required for OTC application and Futura is targeting completion of the FM71 study and Human Factors study for Q2 2022.

#### **US confirmatory clinical study – FM71**

FM71 is a confirmatory clinical study with MED3000 designed to provide supplementary six-month efficacy data with a “least burdensome” approach and modest cost.

FM71 will be of a six-month duration (24 weeks) versus three month duration for FM57 to reassure the FDA that efficacy does not diminish over a longer period of time, although it is Futura’s belief that this is unlikely as in the FM57 study efficacy improved from the first to third month of patient use.

Approximately 100 patients in total will be recruited including a mix of mild, moderate and severe ED sufferers. Recruited patient population will include 20 African American patients (from a leading US medical centre) and 80 patients recruited from Eastern Europe where sites include some of the same centres used in the FM57 trial. No placebo is required hence the study is relatively small in size compared to FM57 where the Company recruited in excess of 1,000 patients. The primary endpoints are a significant change from baseline and exceeding a minimal clinically important difference calculated using the Rosen et al statistical method, a standard assessment technique for measuring Patient Reported Outcomes. Both endpoints were previously met for MED3000 over the 12-week duration of study FM57. Additional statistical study design has been agreed to support a fast speed of onset claim of 5, 10 or 15 minutes (10 minutes was achieved in FM57).

## CHAIRMAN AND CHIEF EXECUTIVE'S REVIEW

A Tadalafil 5mg (the active in Cialis®) comparator arm is included for informational purposes only to assess relative safety, speed of onset and overall efficacy; non-inferiority of MED3000 against Tadalafil is not required to be shown. This will more accurately enable FDA to determine the relative benefit/risk ratio of MED3000 versus a commercially available comparator.

### **MED3000 commercialisation plans**

As regulatory processes continue Futura has been working with retained specialised corporate advisers on active commercial discussions with potential licensing and marketing partners in line with an agreed process being managed by the advisers.

Futura announced in late October 2020 that it had given priority to certain negotiations for one specific region for the exclusive marketing rights for MED3000, with certain parties. These discussions were formalised in early March 2021 with the announcement of investment and joint collaboration with Co-High Investment Management and certain subsidiaries of Atlantis Group to commercialise MED3000 in China and South East Asia.

Futura is making steady progress on commercial discussions for MED3000 marketing rights in multiple other regions. Partnering discussions generally follow the path of interested parties submitting a non-binding offer which is followed

by an invitation for due diligence of full MED3000-related data under a Confidential Disclosure Agreement and thereafter a formal offer which, if accepted contractually by Futura, would be binding. Currently a number of interested parties have made submissions at the non-binding offer stage with further offers expected, although there can be no guarantee of deal completion at this stage. The Company looks forward to providing further updates in the coming months. Futura is committed to prioritising commercial deals that will deliver long-term and sustainable value to the Company, allowing a long-lasting growth franchise to be built around the pipeline of DermaSys® formulated products and in particular MED3000.





An initial UK patent was filed in December 2019 around MED3000's clinically significant and novel findings shown in FM57. This was supplemented with a further UK patent filing in August 2020 following a complete analysis of all the data sets provided by FM57 and a head-to-toe strategic review conducted by independent pharmaceutical patent specialists retained by Futura. An initial examination report conducted by the UK patent office, requested at the time of the first UK filing by the Company, supports the patentability of the application which is an important first step in the patent approval process. In October 2020 further patent filings were made and in particular a Patent Cooperation Treaty ("PCT") application taking priority from the two earlier UK applications. The PCT currently has 153 contracting countries where the Company can seek patent protection claiming priority from an original application made in any one of the countries that are signatories to the PCT, such as the UK. In Q2 2022 national applications will need to be made and the Company, in consultation with its commercial partners, will decide those countries in which to file applications and considered necessary to protect the commercial interests of MED3000. If national applications are successful this will provide patent protection until 2040.

#### **Co-High Licensing agreement – China and South East Asia**

In March 2021 Futura entered into £1.50 million convertible debt and £0.50 million of warrants financing transactions with HT Riverwood Multi-Growth Fund ("Riverwood"), a fund managed by Atlantis Investment Management Limited ("Atlantis"), a leading asset manager, which has provided the Company with £2 million in cash.

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.

Additionally, Futura entered into a licensing agreement with Pride Century Ventures, a special purpose vehicle owned by Co-High Investment Management Limited ("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. 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 regional profits from the commercialisation of MED3000 (the "Joint Collaboration") including any profits derived from local partner agreements within the Region.

Atlantis is a leading international asset management company with a focus in the Greater China Region and South East Asia. Co-High is a specialist private equity company in the Greater China region and invests into 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.

#### **TPR100 – Futura's advanced proprietary transdermal technology, DermaSys® for transdermal delivery of diclofenac for the pain and inflammation associated with sprains, strains and bruises and soft tissue rheumatism**

TPR100 is a proprietary DermaSys® product formulation engineered to achieve targeted and controlled permeation of diclofenac through the skin for local relief of pain and inflammation associated with soft tissue damage caused by sprains, strains, bruises and rheumatism. It is partnered for manufacturing and distribution in the UK with Thornton & Ross, one of the UK's largest consumer healthcare companies and a subsidiary of STADA AG.

Futura has completed additional laboratory formulation adjustment and work specifically around the skin permeation characteristics of TPR100 in response to the UK MHRA's questions after Thornton & Ross' initial filing of a UK marketing authorisation application.

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



## CHAIRMAN AND CHIEF EXECUTIVE'S REVIEW



Since Voltaren® 1% has recently gained OTC status in the US a new and attractive potential market opportunity has arisen in that geography for TPR100. Futura is therefore exploring designs, funds permitting, for a clinical study to achieve approval for a superior product without a prescription in the US as well as fulfilling data requirements for UK and EU regulatory submissions as a topical pain relief and anti-inflammatory treatment.

Commercial discussions with several potential distribution partners for other countries continue however, any further licensing deals are expected to be after a regulatory approval is achieved.

### **CBD100 – Futura's advanced proprietary transdermal technology, DermaSys® for the delivery of cannabidiol**

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

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.

Completion of initial laboratory and optimisation work on CBD100 was announced in August 2020.

As part of a robust formulation process using strict pharmaceutical development principles, Futura carried out extensive DermaSys® cannabidiol formulation work and initial in vitro tests on human epidermis during 2020. The studies 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 used in gels and other topically applied forms. CBD100 was specifically formulated to minimise this issue and has shown encouraging early stability work, which is expected to ensure potency is retained during shelf-life.

The Futura R&D team's development work on CBD100 is further evidence of the broad utility and power of the DermaSys® system for effective and controlled transdermal delivery of a wide range of active pharmaceutical ingredients.

An intellectual property application was made in August 2020 covering various unique aspects of the CBD100 gel formulation. Initial patent office examination has suggested that CBD100 is a novel and inventive formulation and the patent application is expected to progress into the international Patent Cooperation Treaty (PCT) stage in summer 2021.

Cannabidiol is a major component of the cannabis plant and 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. The market for cannabidiol products is growing rapidly. A report by Reports and Data estimates that the market for cannabidiol products is forecast to grow from US\$1 billion in 2018 to US\$16 billion by 2026, at a CAGR of

27.7%, 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.

In conjunction with its joint venture partner Futura is exploring the potential of CBD100 from both a development and commercial standpoint. External advisers with a strong commercial track record, experience and credentials in the cannabis-derived active ingredients market have been appointed. A structured process is ongoing for validating and understanding CBD100's market potential, where the best commercial opportunity lies and then development requirements prior to planning and execution of further work. The finalisation of plans will be defined by ongoing regulatory changes that are occurring with respect to marketing authorisation requirements for cannabidiol. For example, the EU is set to provide a regulatory update for cannabidiol use in cosmetics during 2021. Futura plans to update shareholders in due course.

In light of increasing regulation, a gel that has been formulated using strict pharmaceutical development principles with strong delivery characteristics, stability and high quality could 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 however, it is likely that a "cosmeceutical" will be developed first.

The route to an approved cosmetic product is expected to be fastest where there is a large existing market opportunity but with lower barriers to entry where quality and differentiated brand attributes are important. Whilst a pharmaceutical development route for an effective cannabidiol gel remains of significant potential, it also involves higher risk and cost until the clinically proven benefits of cannabidiol and specific indications to which it is applicable are better understood.

#### FINANCIAL REVIEW

The £2.00 million cash investment arising from the MED3000 collaboration agreement for China and South East Asia post year end in March and April 2021, in addition to a year end cash balance of £1.02 million and usual refund of R&D tax credits of £0.52 million, will fund the Company's working capital through to Q1 2022, with a focus on formalising further MED3000 partnering and license agreements in additional regions, particularly where marketing approval is near-to-medium term.

#### OUTLOOK

Futura has achieved major milestones in terms of securing partnering for the development and commercialisation of MED3000 in China and South East Asia in a deal structured to capture significant long-term value, as well as the EU Notified Body's recommendation to certificate MED3000 for Class 2B approval as a medical device for ED treatment under the European Medical Device Regulations.

The Company is well positioned to deliver further positive news through 2021. Futura expects the final certificate of EU CE mark approval for MED3000 by the end of May and the team is focused on preparation and execution of the confirmatory clinical study and non-clinical studies to finalise an OTC label for the regulatory submission for MED3000 in the US which the Company aims to achieve in 2022. Furthermore, given the potential for expedited Medical Device Registrations possible in most Middle East, Far East, African and Latin American countries based on EU CE mark Futura looks forward to achieving additional progress in a worldwide roll out of registrations followed by commercialisation of MED3000 as a fast-acting topical ED treatment without the need for a physician prescription. The rapidly solidifying potential of MED3000's value also means that the Company looks forward to being able to update shareholders on the progress of commercial licensing discussions in the coming months.

#### JOHN CLARKE

Chairman

#### JAMES BARDER

Chief Executive

1. Under Brexit terms Northern Ireland is exempt.
2. Manufacturers' Selling Prices 2018: Data available for 75 countries, IQVIA IMS Health.
3. Cello Health Consulting research conducted in the US, France and Germany, commissioned by Futura Medical, 2017.
4. EMA, Withdrawal assessment report for Viagra, 2008.
5. Data for 16 key markets, Global Data Epidemiological Analysis 2020.
6. Nguyen Sex Med Rev. 2017 Oct, vol 5, 508-520.

## 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 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.

### 2020 priorities and performance

### 2021 focus

Invest	<p>→ The regulatory dossier for MED3000 was submitted in the EU and three pre-submission meetings took place with the FDA in 2020 with a further meeting in February 2021.</p>	<p>Commencement of Phase 3 clinical study FM71 required for the US submission and licensing agreements following the recommendation by the EU Notified Body of MED3000 for approval as a medical device.</p>
Innovate	<p>→ The regulatory strategy for MED3000 as a medical device available without the need for a doctor's prescription was defined and accepted by both the EU and US regulatory authorities, with MED3000 having the potential to be the first OTC treatment for ED in the US and most countries around the world.</p>	<p>Resources are focused on the commencement of FM71 and the commercialisation of MED3000.</p>
Improve	<p>→ We raised awareness of the mode of action of MED3000 and the unique benefits of MED3000 for ED sufferers.</p>	<p>Ensure ED sufferers can have access to MED3000 as quickly as possible and continue to develop CBD100 with our partner CBDerma Technology.</p>
Increase	<p>→ We raised the profile of MED3000 as a commercial asset and are in active discussions with potential partner(s) for the licensing rights.</p>	<p>Out-license the rights to MED3000 for optimal sustainable long-term value for shareholders.</p>

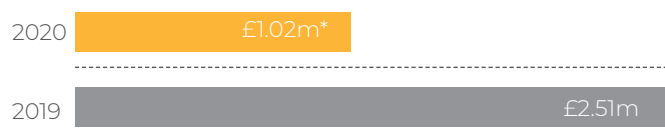
## KEY PERFORMANCE INDICATORS

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.

### GROUP CASH

£1.02m  -59%



\* A further £2.00 million was raised post year end

### ADMINISTRATION AND CENTRAL OVERHEAD SPEND

£1.00m  -12%



Given the funding requirements of the business to ensure completion of the development programmes, cash is considered to be a key metric.

We operate as a "semi-virtual" company and keep tight control of central costs. The spend was broadly in line with the previous year and demonstrates our commitment to keep central costs low.

### RESEARCH AND DEVELOPMENT COSTS

£1.93m  -81%



We invest in Research and Development ("R&D") to generate future revenue and value from our assets. The decrease in 2020 is related to the shift of activities from clinical development to regulatory and manufacturing activities linked to MED3000.

### Non-financial measures – Headcount

#### R&D

8

(2019: 8)

#### CENTRAL

2

(2019: 2)

#### EXECUTIVE DIRECTORS

3

(2019: 3)

The Group is focused on the development of its lead asset MED3000 and the tight control of central costs.



PORTFOLIO REVIEW – MED3000

# MED3000

## A topical gel for the treatment of erectile dysfunction

### MARKET OVERVIEW

One in five men suffers 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 by 2025<sup>2</sup>. Erectile dysfunction 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 access to pornography. Erectile dysfunction can lead to low self-esteem, 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 increased awareness in the general public of this significant problem.

Despite their success PDE5i's have certain limitations. Although proven

highly efficacious, oral PDE5i's have several adverse effects as well as 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 pre-planning for sexual intercourse. Viagra® for example only starts to work in 30-60 minutes. As a result many men and their partners are dissatisfied with PDE5i's and it has been estimated that almost 50% discontinue use after one year<sup>3</sup>. In most countries oral PDE5i's are only available as a prescription-only product which presents too high a barrier for many men who are too embarrassed to seek treatment, for whom the process is not convenient enough or who find the cost of the physician and medicine prohibitive in countries such as the US.

### ED SUFFERERS' UNMET NEEDS

There has been little effective innovation in over ten years for the treatment of ED. Today, there remains a significant unmet clinical need for those men wanting a fast-acting treatment that can give greater

MED3000 IS A  
**US\$1 billion**  
MARKET OPPORTUNITY<sup>B</sup>

- The ED prescription market is worth **US\$5.6 billion** (2018)<sup>A</sup>
- Oral PDE5i's are the first line of treatment. They are effective but don't meet the needs of many men with ED.
  - Almost **50%** of ED patients discontinue therapy after one year<sup>5</sup>
  - Around **20%** of ED patients cannot take oral PDE5i's as they are contraindicated with other medicines they take<sup>6</sup>
  - Only **1 in 4** men diagnosed with ED in the US is on treatment<sup>7</sup>
- There has been **limited innovation** in the treatment of ED in over ten years. There are **clear unmet** medical needs.
- **US\$560 million** potential prescription peak sales at US\$5 per dose<sup>8</sup>  
Research by Cello and model provided by Decision Resources for Futura
- **US\$660 million** potential "over-the-counter" sales at US\$5 per dose with **70%** incremental to prescription sales<sup>8</sup>  
Research and forecast provided by Ipsos Group for Futura



## ERECTILE DYSFUNCTION – AN UNMET MEDICAL NEED

- Erectile dysfunction affects around 50% of men between 40 and 70 years old<sup>9</sup>. ED is an indicator of other serious conditions such as diabetes and heart disease.
- Both severity and prevalence of ED increase with age – a factor of great consequence given our ageing population.
- The relationship between ED and other disorders such as obesity and diabetes, which are themselves reaching epidemic proportions, may also contribute to the increase in ED worldwide.
- ED is increasingly affecting younger men with the prevalence of ED in young men being as high as 30%<sup>10</sup>.
- Many ED sufferers do not seek treatment. In addition, over two thirds of men who have discussed their condition with their physician are not on treatment<sup>11</sup>.
- For those who go on treatment, discontinuation rates for long-term therapy are high with almost 50% of men stopping treatment after one year<sup>5</sup>.

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.

## MED3000 – AN INNOVATION IN THE TREATMENT OF ED

MED3000 is a treatment applied directly to the glans or head of the penis for 15 seconds. Because it's a gel it means that men with 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. Registration as a medical device means MED3000 will be the first pan-European topical treatment for erectile dysfunction available without the need of a doctor's prescription and has the

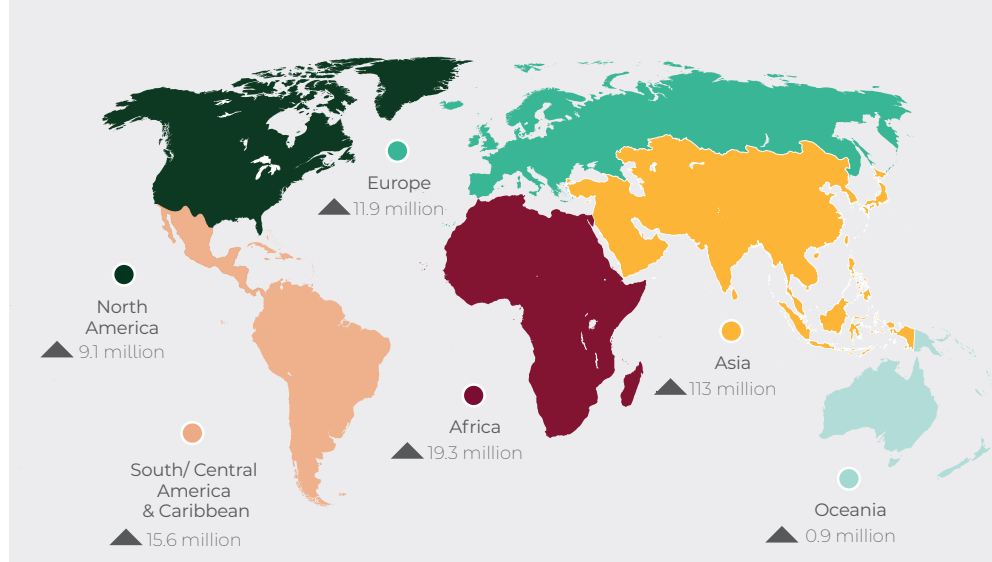
potential to be the first clinically proven treatment available over-the-counter in the US, with potential global peak sales of over US\$650 million<sup>8</sup>.

## KOL ENGAGEMENT PROGRAMME

Futura has engaged 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 programme. 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 2021 and beyond. There has been growing interest from leading Key Opinion Leaders in our topical treatment because it offers a novel and unique treatment that could address patients' unmet needs.

1. EMA, Withdrawal assessment report for Viagra, 2008
2. Adapted from McKinlay JB. Int J Impot Res. 2000; 12 (suppl 4): S6-S11
3. Corona G., "First-generation phosphodiesterase type 5 inhibitors dropout: a comprehensive review and meta-analysis", *Andrology*, 2016, 4, 1002-1009
4. Manufacturers' Selling Prices 2018: Data available for 75 countries, IQVIA IMS Health.
5. Corona G., "First-generation phosphodiesterase type 5 inhibitors dropout: a comprehensive review and meta-analysis", *Andrology*, 2016, 4, 1002-1009
6. Cello Health Consulting research conducted in the US, France and Germany, commissioned by Futura Medical, 2017.
7. Frederick L., "Undertreatment of erectile dysfunction: claims analysis of 6.2 million patients", *J Sex Med*, 2014, Oct, (10):2546-53;
8. Previous market research conducted by Cello Health Consulting as a prescription product and Ipsos Group as an over-the-counter product on MED2005 showed potential peak sales in excess of US\$1 billion. 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.
9. Feldman HA et al. *J Urol* 1994; 151: 54 – 61
10. Nguyen *Sex Med Rev*. 2017 Oct, vol 5, 508-520
11. Jannini *J Sex Med* 2014 Jan; 11(1):40-50

## ED SUFFERERS PREDICTED TO INCREASE FROM 152 MILLION TO 322 MILLION BY 2025<sup>2</sup>



## PORTFOLIO REVIEW – MED3000

### 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 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 products to improve overall efficacy to 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 dysfunction. 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 fast-acting 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.

**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, double-blind, 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 oral tablets with significant benefits for spontaneous rather than pre-planned sexual intercourse.

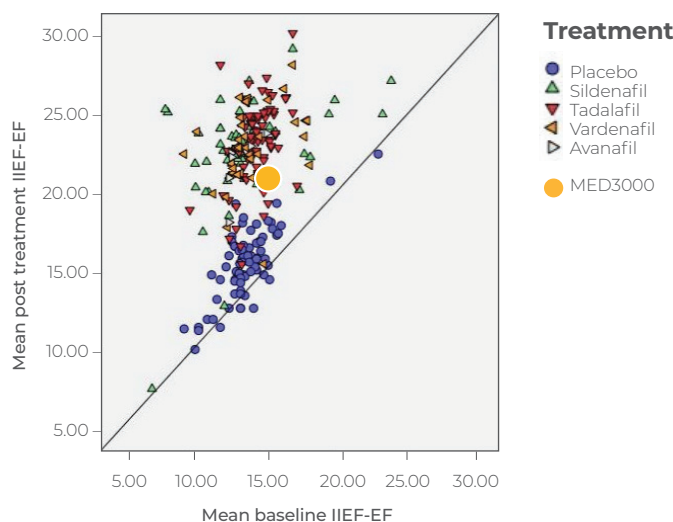
**MED3000'S EFFICACY AND SAFETY COMPARED TO ORAL PDE5I'S AND LOW DOSE CIALIS®**

The construct of clinical study FM57 was very similar to the design used to study a variety of PDE5i's. In particular, the main co-primary endpoint, the International Index of Erectile Function-Erectile Function domain, "IIEF-EF", which is fully validated, has been used to compare pre and post-treatment ED in many studies. Using this assessment, it is possible to compare the efficacy achieved with MED3000 in FM57 with historical data reported in the literature. The scatter plot below compares pre and post treatment IIEF-EF scores for MED3000 against the many studies of PDE5i's and the corresponding placebos used in these historical studies. From this analysis, we conclude that MED3000's efficacy is broadly equivalent to the efficacy achieved with lower doses of oral PDE5i's.



**MED3000 COMPARATIVE EFFICACY TO PUBLISHED DATA ON PDE5I'S**

This scatter plot contains studies of broadly equivalent design measuring IIEF-EF but may vary in terms of study design and population groups<sup>12</sup>. This is for illustrative purposes only as the data is derived from different clinical studies.



<sup>12</sup> Burnett AL, Nehra A, Breaux RH et al: Erectile dysfunction: AUA guideline. J Urol 2018; 200: 633.



## PORTFOLIO REVIEW – MED3000

The table below compares the improvement in efficacy for MED3000 and low dose Cialis® compared to baseline from historical data reported in the literature. The parameters include IIEF-EF as well as the validated measures the Sexual Encounter Profile (SEP) Question 2 and 3. MED3000 shows clinical trial efficacy results that are broadly equivalent to those of Cialis® 5mg.

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. The second table below compares the side effects profile for men for MED3000 and reported data for Cialis® 5mg with an occurrence over 2%.

PRIMARY EFFICACY PARAMETERS	MED3000	MED3000	MED3000	CIALIS®	CIALIS®	CIALIS®
	Baseline	12 weeks	Change from Baseline	5mg (tadalafil) Baseline (Non-US Phase 3 studies)*	5mg (tadalafil) 12 weeks (Non-US Phase 3 studies)*	5mg (tadalafil) Change from Baseline (Non-US Phase 3 studies)*
IIEF	16.5	21.6	5.1	13.1	17.7	4.6
SEP2 (Were you able to insert your penis into your partner's vagina?)	62%	86%	24%	41%	57%	16%
SEP3 (Did your erection last long enough for you to have successful intercourse?)	22%	59%	37%	18%	40%	22%
ADVERSE EVENTS	MED3000** (N=250)		CIALIS® 5mg (tadalafil) (N= 151)*			
Headache	3%		11%			
Flushing	–		2%			
Nasal congestion	–		2%			
Back pain	–		3%			
Myalgia	–		2%			

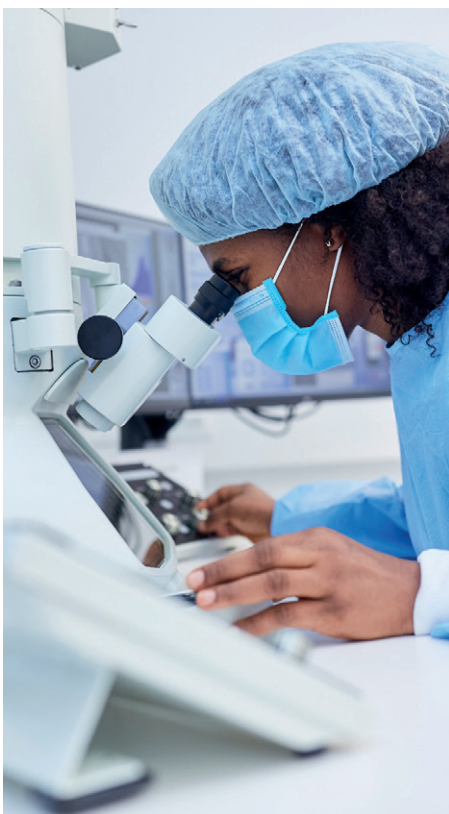
\* For illustrative purposes only as data is derived from different clinical studies – Cialis® data from 2 non-US Phase 3 studies. Cialis® US Prescribing information, 2018.

\*\* Users of MED3000 noticed 1.2% penile burning in men and 0.4% vulvovaginal burning in women.

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

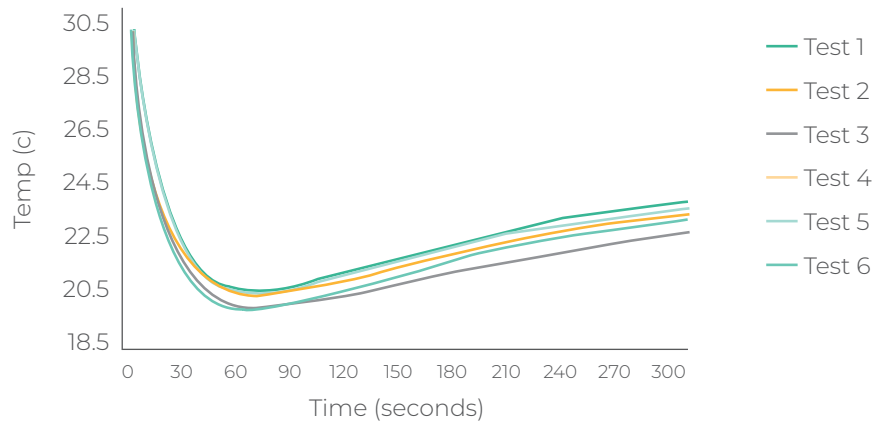
MED3000 works through a unique mode of action. MED3000's combination of volatile solvent components creates an evaporative action that stimulates nerve sensors in the highly innervated glans penis by a cooling and recovery warming effect, rapidly leading to smooth muscle relaxation, tumescence and erection 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 in 2020 which demonstrated the mode of 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.

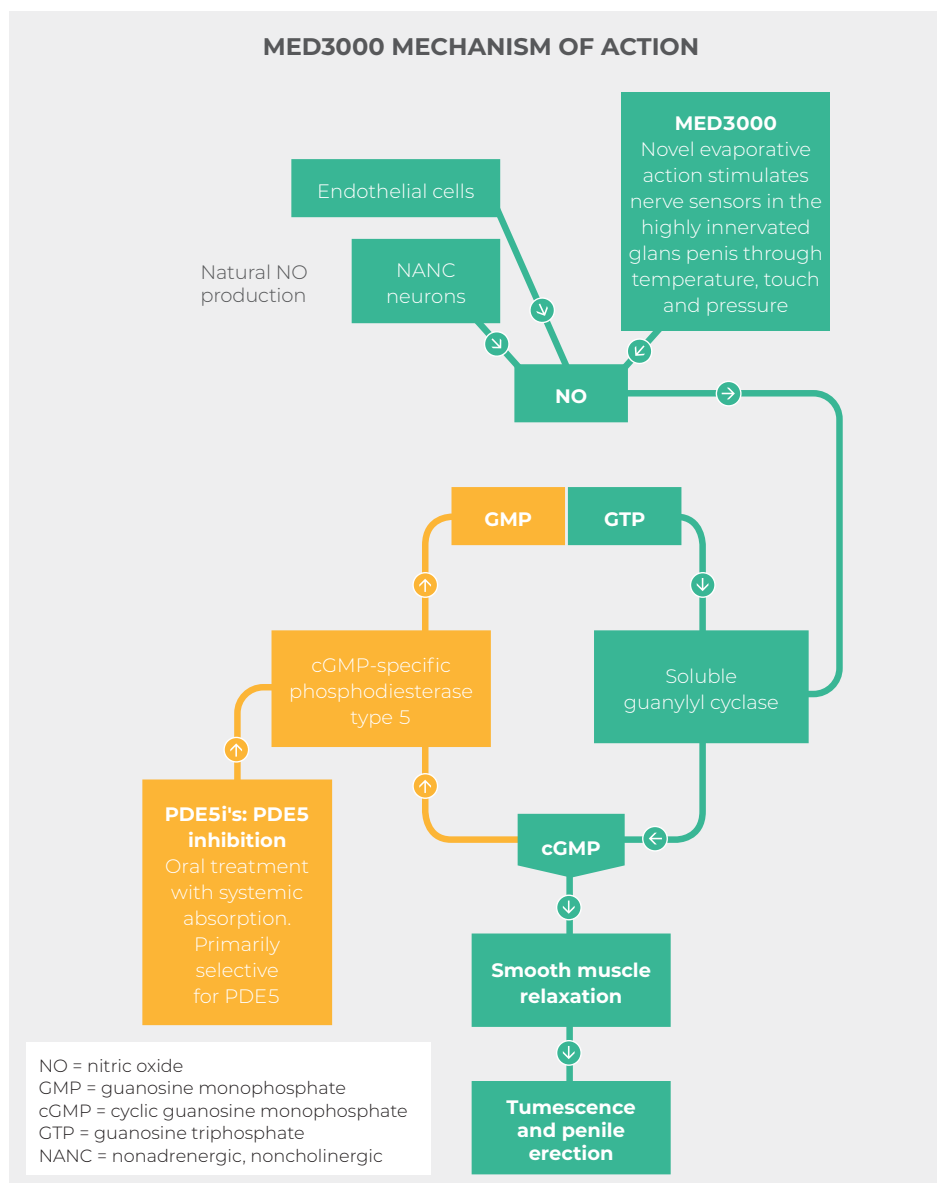


**MED3000'S RAPID COOLING AND RECOVERY WARMING ACTION**

Projected temperature change when MED3000 is applied to the glans penis.



**MED3000 MECHANISM OF ACTION**



# PORTFOLIO REVIEW – MED3000

## A YEAR OF GREAT PROGRESS CULMINATING IN THE RECOMMENDATION OF MED3000 BY THE EU NOTIFIED BODY FOR APPROVAL IN THE EU POST PERIOD END

2020 has been a year of tremendous progress from a regulatory perspective. In the first quarter Futura continued the analysis of the data from the clinical trial FM57 which completed in December 2019 and focused on defining the regulatory strategy for MED3000 which resulted in Futura successfully making the case to EU and US regulatory agencies for MED3000 to be classified as a medical device available without the need for a doctor's prescription (OTC). Futura has proactively worked with EU and US regulatory authorities and made great progress with the recommendation of MED3000 by the EU Notified Body for approval in the EU post period end as a Class 2B medical device. Registration as a medical device means MED3000 will be the first pan-European topical treatment for erectile dysfunction available without the need of a doctor's prescription (OTC). This classification also offers the potential for MED3000 to be the first over the counter treatment in the US, the largest market. The EU CE mark will also enable us to fast-track approvals in many other geographies, including most Middle East, Far East, African and Latin American countries through an expedited regulatory process.

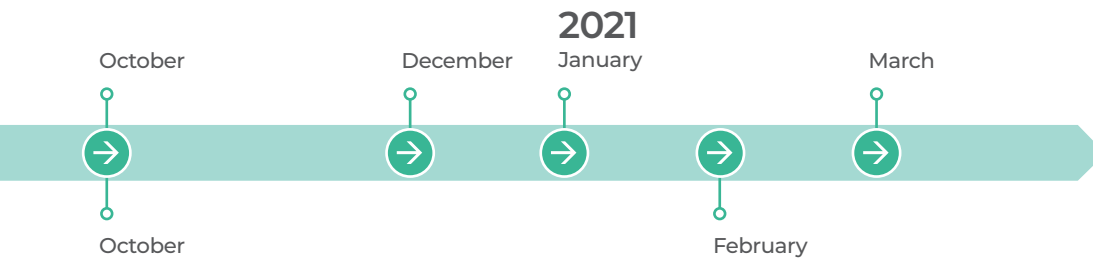
### MED3000 REGULATORY PROGRESS



### EU



\* Notified Bodies are organisations designated by EU countries to oversee the approval of medical devices within the EU and the UK.



## US

February 2020	➔	<b>1st</b> Pre-submission Meeting with FDA FDA agrees to a De Novo medical device application
July 2020	➔	<b>2nd</b> Pre-submission Meeting with FDA Pathway to a marketing approval for MED3000 in the US has been established, and importantly, potential for over-the-counter designation without the need for a doctor's prescription. FDA confirmed requirement for a further smaller supplementary study
October 2020	➔	<b>3rd</b> Pre-submission Meeting with FDA Preliminary agreement on the design and scope of the required small supplementary study (100 subjects), known as "FM71"
February 2021	➔	<b>4th</b> Pre-submission Meeting with FDA Agreement on outstanding points related to the FM71 study and confirmation of next steps. A 5th pre-submission Meeting with FDA is planned for H2 2021 to define and confirm the detail of the work required for OTC application

### MAKING THE CASE FOR OVER-THE-COUNTER AVAILABILITY

Futura has successfully made the case with the EU Notified Body and the US FDA that MED3000, thanks to its unique mode of action, is a medical device. MED3000 is a Class 2B medical device in the EU and in the US the application will be for a medical device with a De Novo classification. This is a unique regulatory strategy which gives MED3000 a faster pathway to regulatory approval and paves the way for MED3000 to be the first treatment available for erectile dysfunction over-the-counter (OTC) in the US. A short, non-clinical, Human Factors Study, testing ease of patient understanding of an OTC label and product administration and use is also required to support the submission and facilitate OTC status as well as a finalised OTC product label.





## PORTFOLIO REVIEW – MED3000

### CONSTRUCTIVE APPROACH FROM FDA

The United States Food and Drug Administration (FDA) has and continues to provide constructive comments and has encouraged Futura to continue the dialogue throughout the pre-submission process on the development of the clinical data, label and other regulatory dossier considerations. The FDA favours an interactive dialogue through the development process which aims to facilitate the approval once the dossier is submitted. Futura has had four pre-submission meetings with the FDA who expressed a willingness to work with Futura to develop the least burdensome design for the small supplementary study that they require.

### EXTENSIVE WORK TO COMPLY WITH NEW EU MEDICAL DEVICE REGULATIONS

In order to obtain pre-marketing clearance within the EU under the new Medical Device Regulations (MDR), two requirements have to be met: the submission of the Technical Documentation which includes sufficient efficacy, safety and quality data; and the demonstration that the Company can operate to a high standard of quality through a Quality Management System (QMS). Futura received a positive audit opinion in August 2020 which means that our QMS meets the required standard for the new Medical Device Regulations.

### MED3000 – FM71 PHASE 3 CLINICAL STUDY

Futura has worked proactively with the FDA on the design of the requested supplemental clinical study to provide the FDA with the necessary reassurance of MED3000's efficacy for up to six months. FDA recently endorsed the design of this study, FM71 based on the "least burdensome approach". FM71 will be a multi-centre, randomised, open label, home use, parallel group, clinical study of topically applied MED3000 and oral tadalafil 5mg tablets for the treatment of erectile dysfunction over a 24-week period. The study will include one centre in the US and 24 centres in Central and Eastern Europe (Bulgaria, Poland, Georgia and Slovakia) where sites include some of the same centres used in the FM57 study. The primary objectives will be to demonstrate an improvement compared to baseline in the EF domain of the IIEF in subjects randomised to MED3000 assessed at 24 weeks post randomisation, and to show that the magnitude of this effect is a clinically important difference. These measures were included and exceeded in FM57 although the study duration was 12 weeks, not 24 weeks as requested by the FDA. A secondary objective is to demonstrate speed of onset of action with the time assessed at 5, 10 and 15 minutes.

\* Notified Bodies are the regulatory authorities that oversee the approval of medical devices within the EU for all EU countries.

\*\* 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.

### RECOMMENDATION OF MED3000 BY THE EU NOTIFIED BODY FOR APPROVAL IN THE EU POST PERIOD END

MED3000 was recommended for approval as a medical device in the EU by the EU Notified Body in March 2021 post period end with the issuance of a Medical Device Regulation certificate expected by the end of May 2021\*. A Class 2B approval will by definition be an approval allowing marketing of MED3000 as a non-prescription treatment across the European Union. Futura is working to bring MED3000 to patients in Europe as soon as possible offering them a new and exciting treatment option.

With the EU recommendation for approval and expected CE mark certificate, this also paves the way for rapid 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 in the period leading up to this Futura will secure the new post-Brexit UKCA mark. This will be a streamlined administrative process since the UK application can bridge to the EU approval.

	MEANS OBSERVED CHANGE FROM BASELINE ACHIEVED	FDA REQUIRED MEANS OBSERVED CHANGE FROM BASELINE
IIEF-EF Domain	FM57	FM71
Overall	5.10	4
Mild	3.15	2
Moderate	5.84	5
Severe	12.15	7

The study will include 100 subjects with 50 randomised to MED3000 and 50 to tadalafil 5mg tablets. Approximately 20 subjects will be located in the United States (from a leading US medical centre) to provide reassurance that data generated outside the US is comparable to the US population. As an open-label design the study will be neither placebo controlled nor double-blinded. The lowest "on demand" dose of tadalafil, 5mg (the active in Cialis®) will also be measured against pre-treatment baseline to enable the FDA to compare an overall risk/benefit analysis of the two treatments for the six month period of the study looking at efficacy, speed of onset and safety. This is for informational purposes only and it is not a requirement for regulatory success that MED3000 is shown to be non-inferior to tadalafil. Planning and preparatory activities for FM71 have commenced and the study is expected to complete in Q2 2022.

## COMMERCIAL PROGRESS IN 2020 TO ACCELERATE IN 2021

During 2020, in parallel with the regulatory processes, Futura has been working with retained specialised corporate advisers on active commercial discussions with potential licensing and marketing partners. Discussions continue with a growing number of parties in line with an agreed process being managed by Futura's advisers with the first licensing deal signed. Partnering discussions generally follow the path of interested parties submitting a non-binding offer which is followed by an invitation for due diligence of full MED3000-related data under a Confidential Disclosure Agreement and thereafter a formal offer which if accepted contractually by Futura would be binding. Currently a number of interested parties have made submissions at the non-binding offer stage with further offers expected although there can be no guarantee of deal completion at this stage. Futura is committed to prioritising commercial deals that will deliver long-term and sustainable value to the Company allowing a long-lasting growth franchise to be built around the pipeline of DermaSys® formulated products and in particular MED3000.

As part of building the commercial proposition for MED3000 and supporting its regulatory approval in countries such as the US, Futura has developed a branding proposition "Eroxon®" with an illustrative pack that licensing partners can select to use at their discretion.

An initial UK patent was filed in December 2019 around MED3000's clinically significant and novel findings shown in FM57. This was supplemented with a further UK patent filing in August 2020 following a complete analysis of all the data sets provided by FM57 and a head-to-toe strategic review conducted by independent pharmaceutical patent specialists retained by Futura. In October 2020 further patent filings were made and in particular a PCT application taking priority from the two earlier UK applications which, if granted, will provide patent protection until 2040.

## FIRST COMMERCIAL DEAL SIGNED (POST PERIOD END)

In March 2021, Futura entered into certain financing transactions with HT Riverwood Multi-Growth Fund ("Riverwood"), a fund managed by Atlantis Investment Management Limited ("Atlantis"), a leading asset manager, which provided Futura with £2 million in cash, which has been received.

In addition, Futura has entered into a licensing agreement with Pride Century Ventures, a special purpose vehicle owned by Co-High Investment Management Limited ("Co-High") for the rights to exclusively develop and commercialise Futura's topical erectile dysfunction treatment MED3000 in China and South East Asia. Co-High will provide funding currently estimated to be up to £4 million for the development and regulatory approval of MED3000 in the region and Futura will be entitled to 50% of regional profits from the commercialisation of MED3000 (the "Joint Collaboration").

Atlantis is a leading international asset management company with a focus in the Greater China Region and South East Asia. Co-High is a specialist private equity company in the Greater China region and invests into and collaborates with some of the world's most promising companies which are believed to be poised to enter a significant growth phase.

Under the terms of the agreement, Futura and Co-High will work together to develop and commercialise MED3000 as a clinically proven treatment for ED available without the need for a doctor's prescription

("OTC") throughout South East Asia. This includes the People's Republic of China (including for the avoidance of doubt, Hong Kong, Macau and Taiwan), and South-Eastern Asia including Brunei Darussalam, Cambodia, East Timor, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam (collectively "the Region"). The prevalence of ED amongst adult males is estimated to be 340 million in the top 16 markets worldwide with China ranked first. China and its neighbouring countries which are included in the Region represent a significant opportunity as the economies of these countries continue to outstrip the economic growth of many Western economies.

Co-High, along with its local partners, will be responsible for all costs related to the development and regulatory approval of MED3000, which are expected to be up to £4 million as well as all costs related to the marketing of the product. This is expected to include a pivotal study in order to gain OTC regulatory approval within China, whereas Co-High believes the EU (inclusive of the UK) approval of MED3000, expected this year, will facilitate approval in the other countries within the Region without the need for further clinical development. Futura will provide reasonable ongoing technical support for OTC product development and commercialisation. Profits from the Joint Collaboration will be shared 50:50, including any profits derived from local partner agreements within the Region.



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

PORTFOLIO REVIEW – OTHER PRODUCTS

# 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. Futura has a portfolio of two pain relief products with well characterised active ingredients including diclofenac and ibuprofen but has prioritised its gel containing 1.86% diclofenac known as TPR100. TPR100 is a gel that brings relief for 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. Diclofenac is a non-steroidal anti-inflammatory drug (“NSAID”) used to treat pain and inflammatory diseases and can be taken by mouth or applied to the skin.

Our objective is for TPR100 to be considered a major competitor to the market-leading topical diclofenac treatments such as Voltarol® gel. Topical diclofenac for the treatment of pain relief is widely available throughout the world without the requirement of a doctor’s prescription. Until recently topical diclofenac was only available with a prescription in the US, but in February 2020 it was switched by the US FDA to over-the-counter. This opens up a new commercial opportunity for TPR100 in the US and we will be working with our commercial advisers to understand the commercial opportunity this represents as well as with our regulatory consultants and the FDA to understand the requirements for approval in the US.

UNMET NEED	INSIGHTS	FUTURA’S PROPOSITION
<ul style="list-style-type: none"> <li>■ Efficacy can be poor due to inadequate penetration</li> <li>■ Treatment required to be applied 2 to 4 times daily</li> </ul>	<p>Need for a treatment that:</p> <ul style="list-style-type: none"> <li>■ is easy to apply and doesn’t stick to clothes after it has been applied</li> <li>■ need for a twice daily application regimen to improve adherence</li> </ul>	<p><b>TPR100</b> is a topical 1.86% diclofenac gel for pain relief using its DermaSys® transdermal technology</p>





## PAIN – AN UNDERSERVED MARKET

- Osteoarthritis is a condition that affects the joints, causing pain and stiffness and affecting mobility. It is a degenerative condition with no cure affecting the daily lives of millions and causing joint pain.
- Arthritis is a leading cause of work disability in the US<sup>1</sup>.
- Prevalence is high affecting 23% of all adults – 54 million people have arthritis in the US<sup>1</sup>.
- Musculoskeletal conditions range from those that arise suddenly and are short-lived, such as sprains and strains to lifelong conditions associated with ongoing pain and disability.
- Musculoskeletal conditions are the leading contributor to disability worldwide, with lower back pain being the single leading cause of disability globally<sup>2</sup>.

of questions requiring additional laboratory work specifically around the permeation characteristics of TPR100 to be conducted. Futura has completed this additional laboratory formulation adjustment and work.

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

Since Voltaren® 1% has recently gained OTC status in the US a new and attractive potential market opportunity has arisen in that geography for TPR100. Futura is therefore exploring designs, funds permitting, for a clinical study to achieve approval for a superior product without a prescription in the US as well as fulfilling data requirements for UK and EU regulatory submissions as a topical pain relief and anti-inflammatory treatment.

Commercial discussions with several potential distribution partners for other countries continue however any further licensing deals are expected to be after a regulatory approval is achieved.

1. CDC website
2. WHO website
3. IMS Health Estimate 2015
4. IMS Data source 2015

→ Global OTC sales of topical NSAIDs<sup>3</sup>

>\$2.9bn

→ US Rx sales of topical NSAIDs<sup>4</sup>

>\$1bn

→ Significant opportunity for TPR100

(heat pain tolerance test) and the secondary pain measurement was the level of inflammation (as indicated by erythema, reddening of the skin). The study data was encouraging, with TPR100 achieving efficacy against its clinical endpoints.

## FUTURA DEVELOPMENT AND COMMERCIALISATION

In January 2017, Futura announced a licensing agreement with Thornton & Ross Ltd, the UK subsidiary of international healthcare company STADA Arzneimittel AG, for the commercialisation in the UK of TPR100. Under the terms of the agreement, Thornton & Ross Ltd will conduct the manufacturing scale-up of TPR100 and hold rights to manufacture, market and distribute the product in the UK for the lifetime of the product's patents, which run to at least 2028 in the UK. Futura received an upfront payment and will receive a further milestone payment upon the product receiving UK regulatory marketing authorisation along with royalties on product sales.

In July 2018, Thornton & Ross Ltd submitted a product licence application to the Medicines and Healthcare products Regulatory Agency ("MHRA") for the marketing authorisation of TPR100 in the UK. In February 2019, the MHRA responded to Thornton & Ross with a number

## DEVELOPMENT

In 2015, a randomised, double blind, crossover clinical proof of concept study in 20 healthy volunteers was conducted using a model of induced pain. The skin of healthy volunteers was carefully exposed to a controlled amount of ultra-violet light to increase the sensitivity of the skin to pain stimuli. The effect of TPR100, Voltarol® gel and a placebo gel were assessed over a six-hour time period post dosing using two criteria: the primary pain measurement was the volunteers' sensation of pain



## PORTFOLIO REVIEW – OTHER PRODUCTS

# CBD100

## DermaSys® for the delivery of cannabidiol

Futura announced a joint venture collaboration with CBDerma Technology Limited in September 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 report by Reports and Data forecasts that the market for cannabidiol products is forecast to grow from US\$1 billion in 2018 to US\$16 billion by 2026, at a Compound Annual Growth Rate ("CAGR") of 27.7% during the forecast period. The market is primarily driven by the increase in the usage of cannabidiol in medical application, supplements, beverages and skin care.

A recent independent report commissioned 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 use 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 varies also greatly by country in Europe from 7% in France to 33% in Austria.

#### DERMASYS® CANNABIDIOL FORMULATION

DermaSys® may be able to provide a rapid and targeted local delivery of cannabidiol through the skin to the required site of action with a high level of safety and more effectively than other cannabidiol products. 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 DermaSys® cannabidiol formulation work and initial in vitro tests on human epidermis. The studies demonstrate highly efficient penetration 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.

#### 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 will establish early ex vivo proof of concept studies likely to include certain disease states most suited for local or regional (non-systemic) topical treatment such as pain relief. Futura has completed the initial laboratory and optimisation work. 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. We have now started to explore commercialisation options for CBD100 with CBDerma as stability work continues in parallel.

#### 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

## FINANCIAL REVIEW

## ANGELA HILDRETH

Finance Director and Chief Operating Officer



As outlined in the Chairman and Chief Executive's Review, during the year Futura focused its financial resources towards approval and commercialisation of its fast-acting topical treatment for erectile dysfunction ("ED"). As the FM57 study was concluded, activities shifted toward regulatory and manufacturing. With the majority of the work conducted or overseen by in-house personnel already in place, external third party costs were significantly lower than in the prior year.

A fundraise was completed in January 2020 resulting in gross funds of £3.25 million through the combination of subscription for shares through PrimaryBid and institutional placing to allow the Company to proceed with MED3000 regulatory approval as a medical device in the EU and US.

In addition, in March 2021, the Company concluded a further 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 March 2021 the Company was notified that MED3000 had been recommended for approval 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.

**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 accelerate progress towards achieving a significant, continuous revenue stream within a few years. No revenue was recognised in the period.

## Focusing our financial resources towards approval and commercialisation of MED3000

**RESEARCH AND DEVELOPMENT COSTS**

Research and development ("R&D") costs for the period ended 31 December 2020 were £1.93 million, compared to £10.05 million for the period ended 31 December 2019. The decrease of £8.12 million is reflective of the focus towards regulatory and manufacturing activities, which were conducted in-house by existing personnel and significantly reducing the cost of external third party providers.

There was no capitalisation of R&D costs in 2020.

**ADMINISTRATIVE COSTS**

Administrative costs were £1.00 million for the period ended 31 December 2020 compared to £1.14 million for the period ended 31 December 2019 and were reflective of the Company's strategy to keep central costs lean and focus cash resources on delivering the R&D programme.

**TAX**

It is expected that an R&D tax credit of £0.52 million will be claimed in respect of 2020 and the cash refund is expected to be received mid-2021 from HMRC.

**LOSS PER SHARE**

The basic loss per share for 2020 was 0.99p (2019: 4.36p). 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 2020 was £1.02 million (2019: £2.51 million). Gross proceeds of £3.25 million were received in January 2020 and the usual refund of R&D tax credits of £2.22 million was also received in May 2020. Cash burn during the year was £6.77 million (2019: £8.01 million) primarily in relation to the concluding FM57 clinical study and regulatory and manufacturing activities associated with MED3000. Cash burn in relation to R&D activities for 2021 is expected to increase as clinical study costs relating to FM71 are incurred during H2 2021.

**POST PERIOD EVENTS**

The Company concluded funding of £2.00 million in March and April 2021. The COVID-19 pandemic has continued through 2021 and Futura expects the pandemic to have continued limited impact on operations in 2021. Further information in relation to COVID-19 is available in the Key risks and mitigation section on pages 35 to 37.

**ANGELA HILDRETH**

Finance Director and Chief Operating Officer


## KEY RISKS AND MITIGATION

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
<p><b>↓ CLINICAL DEVELOPMENT AND REGULATORY RISK</b></p> <p>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.</p> <p>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.</p> <p>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.</p>	<p>The Group has reduced this risk by developing products using safe, well-characterised active compounds and excipients, 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.</p> <p>The regulatory pathway for our treatment for erectile dysfunction MED3000 has been significantly de-risked with data generated from the Phase 3 study FM57 providing a greater level of confidence of success:</p> <p><b>Efficacy</b></p> <ul style="list-style-type: none"> <li>■ Clinical efficacy was demonstrated against a pre-treatment baseline in FM57 Phase 3 trial in mild, moderate and severe ED sufferers.</li> </ul> <p><b>Safety</b></p> <ul style="list-style-type: none"> <li>■ No treatment related Serious Adverse Events or Reactions were observed in FM57 Phase 3 trial in over 10,000 sexual intercourse attempts. Very favourable adverse event profile.</li> <li>■ No concerns relating to reactions with other cardiovascular medication such as nitrates, alpha-blockers and anti-hypertensives.</li> </ul> <p><b>Regulatory position</b></p> <ul style="list-style-type: none"> <li>■ Recommendation for approval was received by the EU Notified Body in March 2021 to approve MED3000 as a Class 2B medical device.</li> <li>■ Feedback has been received from US Regulators with a clear route to approval identified.</li> </ul>
<p><b>↓ COMMERCIAL RISK</b></p> <p>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.</p>	<p>The Group seeks to reduce this risk by carefully selecting experienced commercial partners, maintaining and developing these relationships and seeking to develop new products of commercial interest to these and other partners.</p> <p>Strong interest has been shown for a clinically proven topical treatment for ED with discussions continuing following the results of the FM57 Phase 3 study where MED3000 was shown to have meaningful clinical benefits in approximately two thirds of patients in treating their ED.</p> <p>Market access work with Key Opinion Leader endorsement and engagement programme is continuing with positive feedback received in relation to the product and the data generated in the FM57 Phase 3 trial.</p> <p>In March 2021, the Company entered into a Collaboration agreement retaining a 50% profit share for MED3000 in China and South East Asia.</p>



## RISKS AND MITIGATION

RISK	MITIGATION
<p> <b>FINANCIAL RISK</b></p> <p>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.</p>	<p>Futura is focusing its financial resources on its lead asset MED3000. The Group successfully completed a fundraising exercise in January 2020 raising £3.25 million to fund the product through to regulatory approval as a medical device in the EU. 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.</p> <p>Additional financing needs are expected to arise in the second quarter of 2022 and the Group continues to pursue other sources of dilutive and non-dilutive fundraising, including seeking business opportunities from potential out-licensing partners, which would enable the Group to support the future costs of development of its products and the ability to commercialise them successfully.</p> <p>Additionally, the Group places considerable emphasis on communication with existing shareholders and potential investors, to maximise the chances of successful future fundraising.</p>
<p> <b>INTELLECTUAL PROPERTY RISK</b></p> <p>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.</p>	<p>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.</p> <p>During the year, the Group filed additional patents for MED3000 relating to erectile dysfunction and will be looking to strengthen this further in 2021. Whilst the Group is confident that the patents will be granted, it cannot guarantee this will be the case.</p>
<p> <b>KEY PEOPLE</b></p> <p>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.</p>	<p>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 based bonus and share options that vest over a number of years.</p>

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
<p> <b>IMPACT OF BREXIT</b></p> <p>The full impact of the UK having left the EU is still uncertain.</p>	<p>The impact of Brexit has been considered and the following has been assessed and concluded that there will be minimal to no impact.</p> <p><b>Regulatory strategy</b></p> <ul style="list-style-type: none"> <li>■ The EU Notified Body has confirmed that the UK will be included in the approval until 2023. The Company will need to apply for a UKCA in the meantime. This will be a streamlined process since it is understood the UK application can bridge to the EU approval.</li> </ul> <p><b>Clinical trial data</b></p> <ul style="list-style-type: none"> <li>■ We currently have no reason to believe that the UK regulator will insist on clinical trial data generated in the UK. Data generated in six EU and three non-EU countries is expected to continue to be deemed suitable for inclusion in the approval submission.</li> </ul> <p><b>Patent protection</b></p> <ul style="list-style-type: none"> <li>■ Our current assessment is that UK companies will continue to be included within the European Patent Office.</li> </ul> <p>Clearly uncertainty around the full impact of Brexit remains 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.</p>
<p> <b>IMPACT OF COVID-19</b></p> <p>The full impact of the COVID-19 pandemic remains uncertain.</p>	<p>The impact of COVID-19 has been considered and the Directors do not believe that Futura will be significantly impacted during 2021. This is based on the following assessments:</p> <p><b>Operational activities</b></p> <ul style="list-style-type: none"> <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 subcontractors. 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> <li>■ The FM71 clinical study is scheduled to begin H2 2021 across Eastern Europe and the US, subject to funding. COVID-19 is not expected to impact on study recruitment but until site feasibility has been conducted, this cannot be guaranteed.</li> <li>■ There is a possibility that COVID-19 may impact on the timelines with Regulators. The EU Regulator has consistently met its timelines and the US Regulator has not yet advised of any delays to its timelines. We will keep this under review.</li> <li>■ COVID-19 may impact on the Group's ability to raise further finance but given that we do not have an immediate requirement for funding as we are funded until Q1 2022 and funding could come from a number of sources, this is something we will keep under review. The current cash runway does not assume any income from revenue or licensing payments which could be delayed as a result of COVID-19.</li> </ul>

## SUSTAINABILITY REVIEW

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

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 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:

### KEY SDG GOALS WHERE WE CAN HAVE THE GREATEST IMPACT





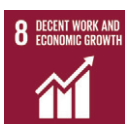
**GOOD HEALTH AND WELL-BEING**

- 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 in the current pandemic this has never been more important. We have supported our staff to work from home and given them the flexibility to balance their work and family commitments and implemented a COVID-secure workplace with thorough risk assessments updated as and when Government guidance changes.



**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 semi-virtual structure supports economic and infrastructure development through the outsourcing of numerous activities including clinical research, statistical analysis, manufacturing, analytical testing and laboratory work. If we are successful with our products this creates more opportunities for our partners.



**DECENT WORK AND ECONOMIC GROWTH**

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



**GENDER EQUALITY**

- We believe in a diverse and gender balanced workforce. We are committed to supporting employment policies and practices that make provision for equal opportunities and non-discrimination in our workforce. We have a balanced workforce with near equal number of men and women in our R&D team, as well as across the Group.

**TOTAL WORKFORCE GENDER SPLIT**





## 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 2020 was more 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

The Board naturally considers its shareholders to be key stakeholders of the Company and is focused upon delivering long-term value for their benefit. The Company engages with its shareholders and potential shareholders on a regular basis with investor meetings throughout the year as well as



focused roadshows at the time of our published results. The results of this investor engagement are reported to the Board to help inform our strategy and communications. 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 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.

### EMPLOYEES

The Board considers its employees to be a primary stakeholder of the Company and is conscious of the regard it has to them under s172. The Board, and especially the Remuneration Committee, have also had particular regards to employees as they 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

Our purpose is clear, “to enhance our patients and consumers’ quality of life to enable them to live their lives to the full”. The patients our therapies are designed to treat are at the heart of why we do it. We consult with Key Opinion Leaders regularly, hold Advisory Boards at key stages and conduct market research to help us with patient insights. We are focused on bringing innovative products to market where there are unmet patient needs with existing treatments.



## COMMERCIAL PARTNERS

The Board places great emphasis on selecting the most suitable commercial partners who have the regulatory and commercial expertise as well as the drive and enthusiasm to make our products a success. The Board keeps itself aware of changes in the industry by fostering existing relationships and through extensive networking. 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.



## DEVELOPMENT PARTNERS AND SUPPLIERS

As a semi-virtual company, Futura relies upon its relationships with external service providers, consultants and subcontractors to provide resources on an “as needed” basis. These resources provide the Company with specialist skills and insights as well as additional capacity.



## REGULATORS

Regulators are agencies that regulate medicines and/or medical devices in their territories. They play a leading role in protecting and improving public health and supporting innovation. Key agencies for Futura include the Medicines and Healthcare products Regulatory Agency (“MHRA”; UK), the United States Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA” European Union) and the Notified Bodies in the European Union. 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.



## BOARD OF DIRECTORS

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



### JOHN CLARKE

Non-Executive Chairman

#### Current roles

John Clarke is the Chairman of Futura Medical plc. He chairs the Nominations Committee, and is a member of the Audit Committee and the Remuneration Committee. He is also the Non-Executive Chairman of Science in Sport plc, 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.



### JAMES BARDER

Chief Executive

#### Current roles

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





### ANGELA HILDRETH

Finance Director,  
Chief Operating Officer  
and Company Secretary

#### Current roles

Angela joined the Group in February 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.

#### 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 ten years' strategic and operational financial experience of developing and commercialising pharmaceutical products.



### KEN JAMES

Executive Director  
and Head of R&D

#### Current roles

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

#### Past roles

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

#### Brings to the Board

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



### JONATHAN FREEMAN

Senior Independent  
Non-Executive Director

#### Current roles

Jonathan Freeman is a Senior Independent Non-Executive Director. He chairs the Audit Committee and the Remuneration Committee and is also a member of the Nominations Committee. He is also a Non-Executive Director of Kingswood Holdings Limited.

#### Past roles

Non-Executive Director of Braveheart Investment Group plc, Director of Beeson Gregory, Chief Executive Officer of Syndicate Asset Management plc, a Director of Hume Capital Securities plc and a Director of Bould Opportunities plc.

#### Brings to the Board

Over 25 years of experience in the financial services sector, guidance on City regulatory matters, corporate finance and investor relations.



## 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. 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 four Remuneration Committee meetings during 2020.

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.futura-medical.com](http://www.futura-medical.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 non-pensionable.

#### 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 approximately 1.37% of the issued share capital as at 31 December 2020.

#### 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 Non-Executive Directors and the Chairman are 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 2020 will be settled in April 2021 by the issue of 176,318 shares at 12.24 pence per share. The 2021 award has been determined at 15 pence per share and the Non-Executive Directors will accrue these shares over 2021 and receive them, or such lower number as have accrued if they leave the Group earlier, in January 2022.

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 2020:

	Year ended 31 December 2020						Year ended
	Salary & Directors' Fees £	Bonus £	Share Awards £	Benefits In Kind £	Pension £	Total £	31 December 2019 £
<b>Executive Directors</b>							
James Barder	242,556	64,102	–	2,652	–	309,310	238,245
Ken James	175,782	70,312	–	2,130	–	248,224	172,793
Angela Hildreth	176,580	45,529	–	2,350	15,836	240,295	171,475
<b>Non-Executive Directors</b>							
John Clarke	65,034	–	26,470	–	–	91,504	88,839
Jonathan Freeman	37,025	–	8,819	–	–	45,844	44,509
<b>Totals</b>	<b>696,977</b>	<b>179,943</b>	<b>35,289</b>	<b>7,132</b>	<b>15,836</b>	<b>935,177</b>	<b>715,861</b>

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

There were no settlements under the LTIP in 2020 (2019: £nil).

## REMUNERATION COMMITTEE REPORT

### DIRECTORS' INTERESTS IN SHARES

	31 December 2020		31 December 2019	
	Beneficial Interests	Non-beneficial Interests	Beneficial Interests	Non-beneficial Interests
John Clarke	512,788	–	256,226	–
James Barder	1,093,472	117,500	968,472	117,500
Jonathan Freeman	175,718	–	90,621	–
Ken James	299,581	–	299,581	–
Angela Hildreth	142,857	–	142,857	–
<b>Totals</b>	<b>2,224,416</b>	<b>117,500</b>	<b>1,757,757</b>	<b>117,500</b>

### 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:

	31 December 2020		31 December 2019	
	Options Held	Share-based Payment Expense	Options Held	Share-based Payment Expense
James Barder	1,800,000	26,993	1,750,000	18,410
Ken James	1,040,000	21,594	800,000	14,728
Angela Hildreth	640,000	21,594	400,000	14,728
<b>Totals</b>	<b>3,480,000</b>	<b>70,181</b>	<b>2,950,000</b>	<b>47,866</b>

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	30 September 2023
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
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
<b>Totals</b>		<b>2,364,348</b>			

**DIRECTORS' INTERESTS IN LONG-TERM INCENTIVE PLAN**

The performance milestones, which are non-market related milestones, were not met in 2020 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, to the participants are:

	2021	2022	2023	2024
James Barder	101,535	101,535	101,535	101,535
Angela Hildreth	88,721	88,721	88,721	88,721
Ken James	95,621	95,621	95,621	95,621
John Clarke	88,721	88,721	88,721	88,721
Jonathan Freeman	56,362	56,362	56,362	56,362
Other employees	369,679	369,679	369,679	369,679
At discretion of Remuneration Committee	44,363	44,363	44,363	44,363
<b>Totals</b>	<b>845,002</b>	<b>845,002</b>	<b>845,002</b>	<b>845,002</b>

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.

**JONATHAN FREEMAN**

Chairman of the Remuneration Committee



## CORPORATE GOVERNANCE STATEMENT

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

### 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 2020. 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 assumed 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 require 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](http://www.futuramedical.com). The QCA Code sets out ten principles and in the Corporate Governance Report on pages 49 to 52 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  
13 April 2021



# 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 at least six times per year and 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 market, 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.

At an appropriate stage of development, the Group may choose to realise monetary value from such products via out-licensing deals with pharmaceutical companies with interests in both prescription ("Rx") and OTC products. Alternatively, 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 35 to 37 of our Strategic Report. The key challenge to 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.

## 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. These include the Group's employees, regulators, partners, suppliers and patients involved in the Group's clinical development activities. 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 and 41.

## 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. In 2017, the Board created a Risk and Oversight Committee (ROC) to provide additional oversight of its operational compliance in respect of its assets. In 2020, 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.

## CORPORATE GOVERNANCE REPORT

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 35 to 37 of our Strategic Report.

### PRINCIPLE 5

#### A well-functioning Board of Directors

Futura's Board currently comprises two 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 one additional Non-Executive Director. Details of the Directors who served in the year can be found on page 53.

#### Attendance at Board and Committee meetings

The Board is responsible to the shareholders for 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. During the year the Board met once in person and, as the Board were unable to meet in person due to COVID-19 restrictions, five meetings were held by videoconference. 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	4/4	1/1
Jonathan Freeman	6/6	2/2	4/4	1/1
James Barder	6/6			
Angela Hildreth	6/6			
Ken James	6/6			

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

#### 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. Jonathan Freeman has served on the Board for a concurrent period longer than nine years but on the basis he had no association with, and was independent from the Group at the time of his appointment and, as such, the Directors consider he satisfies the independence criteria set out in the QCA Code. The Chairman considers Mr Freeman's conduct at Board meetings demonstrates continuing independence and represents appropriate challenge to the executives.

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. 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.



	Biotech/ Pharma sector	Financial	General Management	Other public company (Board level)
John Clarke	✓		✓	✓
Jonathan Freeman	✓	✓	✓	✓
James Barder	✓	✓	✓	✓
Angela Hildreth	✓	✓	✓	✓
Ken James	✓		✓	

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.

#### PRINCIPLE 7

##### Evaluation of Board performance

Internal evaluation of the Board, the Committee and individual Directors is undertaken on an annual basis and was recently completed in December 2020 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.

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

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

#### PRINCIPLE 8

##### Corporate culture

The Board recognises that its decisions regarding strategy and risk will impact on the culture of the Group as a whole and that this will impact the performance of the Group. The Board seeks to maintain the highest standards of integrity in the conduct of the Group's operations. An open culture is encouraged within the Group with regular communications 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 twice a year and has responsibility for, amongst other things, reviewing the annual report and accounts and interim statements involving, where appropriate, the External Auditor. The Committee also approves the External Auditor's fees and ensures the Auditor's independence as well as focusing on compliance with legal requirements and accounting standards. It is also responsible for ensuring that an effective system of internal control is maintained. The ultimate responsibility for approving the annual financial statements and interim statements remains with the Board.



## CORPORATE GOVERNANCE REPORT

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

The Group's Auditor is Grant Thornton UK LLP based at 1020 Eskdale Road, Winnersh, Wokingham, RG41 5TS and was appointed in 2019 as part of a tender process. The current Audit partner is Mark Bishop.

### 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 Director(s) 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 50 to 54. 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 Director(s) 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](http://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 2020, 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](http://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](http://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  
13 April 2021

## DIRECTORS' REPORT

### DIRECTORS

The Directors during the year were:

John Clarke	Non-Executive Chairman
James Barder	Chief Executive Officer
Jonathan Freeman	Non-Executive Director
Ken James	Head of R&D/ Executive Director
Angela Hildreth	Finance Director/ Chief Operating Officer

### 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 focus being on sexual health and pain relief management. The Strategic Report on pages 1 to 41 provides a review of the business, including the Group's trading for the year ended 31 December 2020, 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 (2019: £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 44 to 47. 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 44 to 47.

### 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 2020 the Group's expenditure on R&D was £1,927,658 (2019: £10,051,148).

### 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

### SIGNIFICANT INTERESTS

On 31 March 2021 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	21.04%
T Adams	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](http://www.futuramedical.com).

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 benefits 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 customers, is disclosed in the Stakeholders section on pages 40 and 41.

### SUBSEQUENT EVENTS

Funding of £2 million (gross) was completed in March and April 2021. The COVID-19 pandemic arose in February 2020, the impact of this has been considered and we do not expect this pandemic to materially impact on Futura's business in 2021. Further details can be found within the Key risks and mitigation section on pages 35 to 37.

## DIRECTORS' REPORT

### 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.

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

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

### GOING CONCERN

The Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, there is a material uncertainty which may cast significant doubt on the Group's and the Company's ability to continue as a going concern and, therefore, to continue realising its assets and discharging its liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate. Further details can be found in Note 2.2.

### WEBSITE PUBLICATION

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

By order of the Board

### ANGELA HILDRETH

Company Secretary  
13 April 2021

## 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 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](http://www.futuramedical.com).

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

<b>April 2020</b>	Presentation of 2019 Audit Report Review of 2019 audit performance
<b>December 2020</b>	Review of audit planning including audit risk areas for the year ended 2020 Review and confirmation of External Auditor Independence

### 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 2020 is included within the Independent Auditor's Report on pages 56 to 65. Grant Thornton were appointed in 2019 following a tender process. The Partner is Mark Bishop.

### 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.

### JONATHAN FREEMAN

Chairman of the Audit Committee



# INDEPENDENT AUDITOR'S REPORT

to the members of Futura Medical plc

## OPINION

### Our opinion on the financial statements is unmodified

We have audited the financial statements of Futura Medical PLC (the 'parent company') and its subsidiaries (the 'group') for the year ended 31 December 2020 which comprise the Consolidated statement of comprehensive income, the Consolidated statement of changes in equity, the Consolidated statement of financial position, the Consolidated statement of cash flows, the Parent company balance sheet, the Parent company statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in the preparation of the group financial statements is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006. The financial reporting framework that has been applied in the preparation of the parent company financial statements is applicable law and United Kingdom Accounting Standards, including Financial Reporting Standard 101 'Reduced Disclosure Framework' (United Kingdom Generally Accepted Accounting Practice).

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 31 December 2020 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- the parent company financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

## BASIS FOR OPINION

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

## MATERIAL UNCERTAINTY RELATED TO GOING CONCERN

We draw attention to note 2.2 in the financial statements, which indicates that management have made significant assumptions in preparing the financial statements on a going concern basis. As stated in note 2.2, the group has reported cash and liquid resources of £1.02m as at 31 December 2020 and made an operating loss of £2.92m for the year. Following the completion of a £2.0m fundraise post year end it is projected that these cash resources will extend to Q1 2022. The most significant assumptions made in the cash flow forecast prepared by management include their ability to raise further financing. However, there can be no guarantee that the Group will be able to raise sufficient funding from existing and new investors, nor that the Group will be able to secure further strategic collaborations for its product pipeline. These events or conditions, along with the other matters as set forth in note 2.2, indicate that a material uncertainty exists that may cast significant doubt on the group and parent company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

### Our evaluation of management's assessment of the entity's ability to continue as a going concern'

- Our evaluation of the directors' assessment of the group's and the parent company's ability to continue to adopt the going concern basis of accounting included obtaining management's base case cash flow forecasts covering the period from 1 January 2021 to 30 June 2022, which assumed no revenue being generated, assessing how these cash flow forecasts were compiled and assessing their appropriateness by identifying the most significant underlying assumptions, including evaluating management's assessment of the impact of Brexit and Covid and challenging those assumptions;
- Assessing the accuracy of management's forecasting by comparing management's forecasts against post year end actual results;
- Assessing the accuracy of management's past forecasting by comparing management's forecasts for the year to 31 December 2020 to the actual results for that year and considering the impact on the base case cash flow forecast;
- Obtaining management's forecast which assesses the potential impact of not achieving the expected funding as planned. We evaluated management's assumptions regarding the ability to mitigate costs. We considered whether the assumptions are consistent with our understanding of the business derived from other detailed audit work undertaken;
- Assessing the impact of the mitigating factors available to management in respect of the ability to restrict cash impact, including the level of available facilities; and
- Assessing the adequacy of related disclosures within the annual report.

### Our responsibilities

We are responsible for concluding on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the group's and the parent company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our report to the related disclosures in the financial statements or, if

such disclosures are inadequate, to modify the auditor's opinion. Our conclusions are based on the audit evidence obtained up to the date of our report. However, future events or conditions may cause the group or the parent company to cease to continue as a going concern.

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

### OUR APPROACH TO THE AUDIT



Grant Thornton



#### OVERVIEW OF OUR AUDIT APPROACH

Overall materiality:

Group: £133,000, which represents approximately 4.5% of the group's loss on ordinary activities before taxation.

Parent company: £68,000, which represents approximately 0.1% of the parent company's total assets.

The key audit matters were identified as material uncertainty in relation to going concern and the impairment of the investment in the subsidiary in the parent company financial statements.

We performed audits of the financial information of the significant components Futura Medical PLC and Futura Medical Developments Limited using component materiality (full scope audits), and analytical procedures at group level on the financial statements of Futura Consumer Healthcare Limited.

# INDEPENDENT AUDITOR'S REPORT

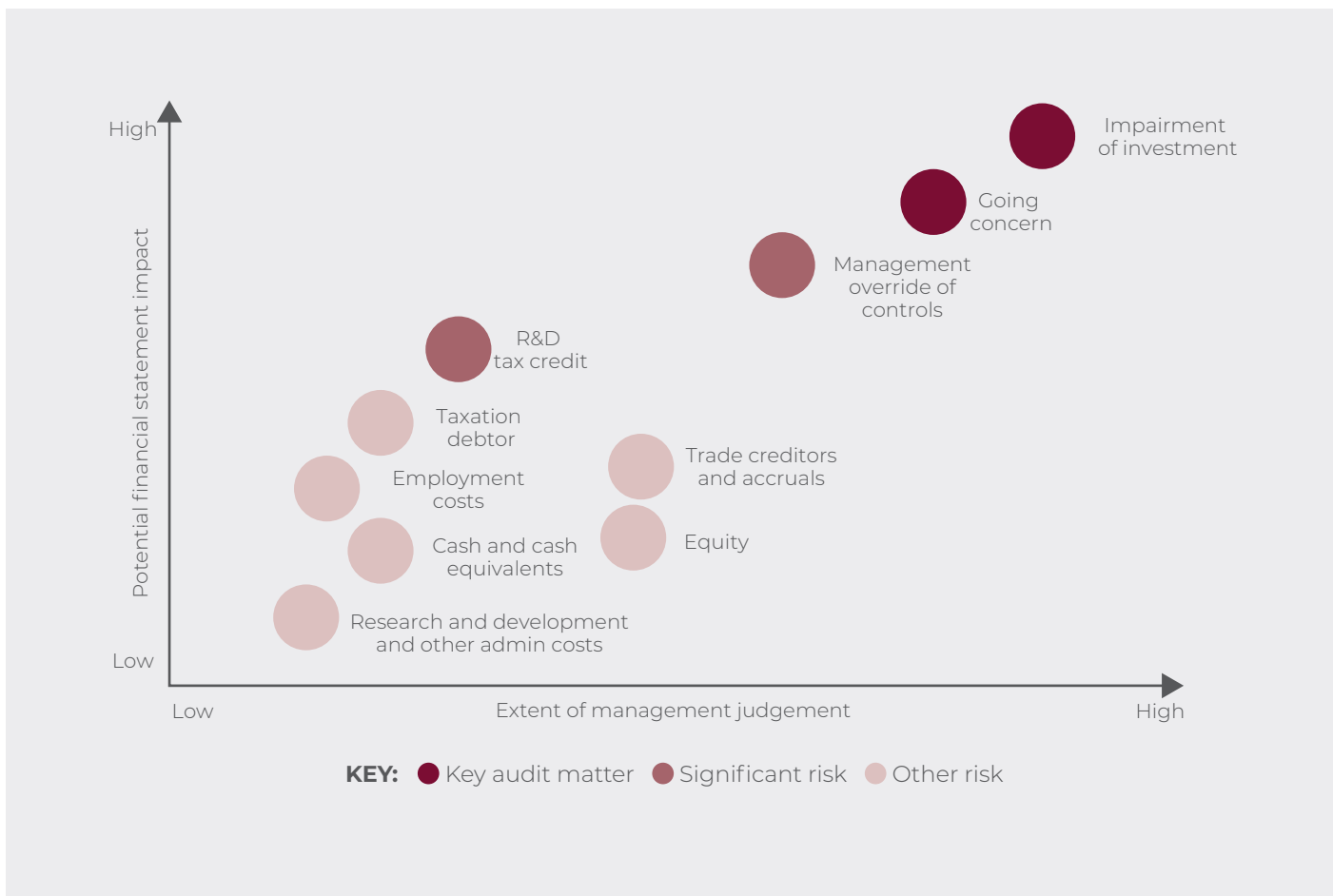
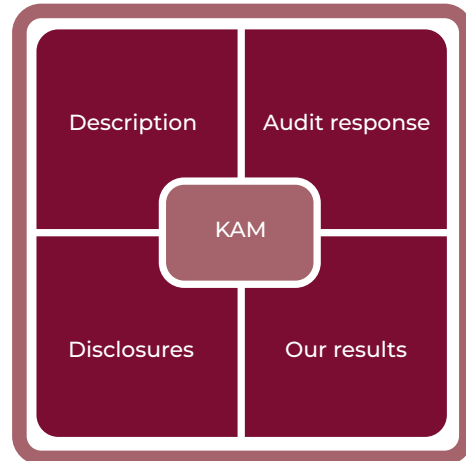
to the members of Futura Medical plc

## KEY AUDIT MATTERS

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

In addition to the matter described in the 'material uncertainty related to going concern' section, we have determined the matter described below to be the key audit matter to be communicated in our report.

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



**Key Audit Matter – Parent company****Impairment of 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 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 – Parent company**

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

- Obtained management's impairment review and compared the recoverable amounts to the value of the investment;
- Inspected 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 the prior year 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.
- Corroborated the key inputs used in support of the key underlying assumptions to relevant supporting documentation; and
- Assessed 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'.

**Relevant disclosures in the Annual Report and Accounts 2020**

Financial statements: Note 2, Investments

**Our results**

Based on our audit work, we are satisfied that the valuation methodologies and assumptions made in management's assessment of goodwill impairment are appropriate. We consider that the group's disclosure to be in accordance with IAS 36 and have found no material errors in calculations.



## 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	Parent company
<b>Materiality for financial statements as a whole</b>	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	£133,000 which represents approximately 4.5% of the group's loss on ordinary activities before taxation. This benchmark is considered the most appropriate because it is a prominent key performance indicator for the users of the financial statements.	£68,000, which represents approximately 0.1% of the parent company's total assets, restricted to be lower than group materiality as it is a component of the group. This benchmark is considered the most appropriate due to the nature of the business.
Significant judgements made by auditor in determining the materiality	<p>The determination of materiality involves the exercise of professional judgement. In determining materiality, we made the following significant judgements:</p> <ul style="list-style-type: none"> <li>■ The selection of an appropriate benchmark;</li> <li>■ The selection of an appropriate percentage to apply to that benchmark; and</li> <li>■ The consideration of other qualitative factors.</li> </ul> <p>We have consistently used loss before tax as the underlying benchmark. We selected this benchmark because the group is predominantly in its pre-revenue phase with the main focus of the group being the expenditure incurred on research and development of the products and obtaining regulatory approval. Loss before tax is also a key performance measure for the company and is therefore of most interest to stakeholders.</p> <p>Materiality for the current year is lower than the level determined for the year ended 31 December 2019 (£547,000) due to a decrease in losses made in the year ended 31 December 2020.</p>	<p>The determination of materiality involves the exercise of professional judgement. In determining materiality, we made the following significant judgements:</p> <ul style="list-style-type: none"> <li>■ The selection of an appropriate benchmark;</li> <li>■ The selection of an appropriate percentage to apply to that benchmark; and</li> <li>■ The consideration of other qualitative factors.</li> </ul> <p>Total assets is considered to be the most appropriate benchmark as the company's purpose is that of holding of investments in subsidiary entities. The company does not undertake any trading activities.</p> <p>Materiality for the current year is lower than the level determined for the year ended 31 December 2019 (£513,000) as a result of the impact of the component materiality restriction applied in the current year.</p>

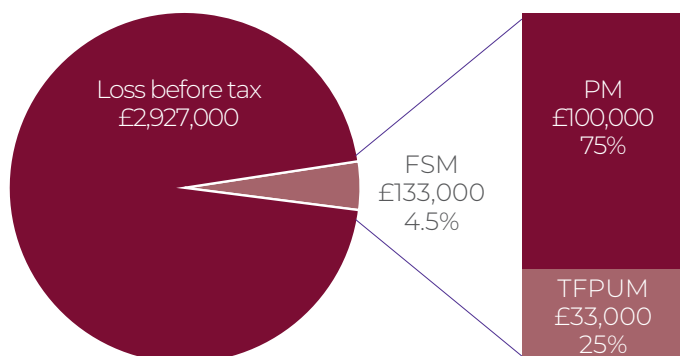
Materiality measure	Group	Parent company
<b>Performance materiality used to drive the extent of our testing</b>	We set performance materiality at an amount less than materiality for the financial statements as a whole to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial statements as a whole.	
Performance materiality threshold	£100,000 which is 75% of financial statement materiality.	£51,000 which is 75% of financial statement materiality.
Significant judgements made by auditor in determining the performance materiality	<p>In determining materiality, we made the following significant judgements:</p> <ul style="list-style-type: none"> <li>■ Our prior year experience with auditing the financial statements; and</li> <li>■ Few adjustments being identified in prior years.</li> </ul>	<p>In determining materiality, we made the following significant judgements:</p> <ul style="list-style-type: none"> <li>■ Our prior year experience with auditing the financial statements; and</li> <li>■ Few adjustments being identified in prior years.</li> </ul>
<b>Specific materiality</b>	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 threshold	We determined a lower level of specific materiality for certain areas such as Directors' remuneration and related party transactions.	We determined a lower level of specific materiality for certain areas such as Directors' remuneration and related party transactions.
<b>Communication of misstatements to the audit committee</b>	We determine a threshold for reporting unadjusted differences to the audit committee.	
Threshold for communication	£7,000 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.	£3,400 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.

## INDEPENDENT AUDITOR'S REPORT

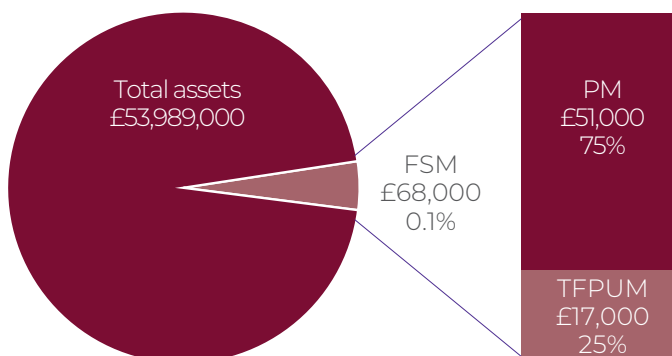
to the members of Futura Medical plc

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

### OVERALL MATERIALITY – GROUP



### OVERALL MATERIALITY – PARENT COMPANY



FSM: Financial statements materiality  
PM: Performance materiality  
TFPUM: Tolerance for potential uncorrected misstatements

### AN OVERVIEW OF THE SCOPE OF OUR AUDIT

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

#### Understanding the group, its components, and their environments, including group-wide controls

- Evaluation of the group's internal control environment and documenting our understanding of controls relevant to the audit.
- Performing walkthrough testing to evaluate the design and implementation of controls relevant to the key audit matters and certain other risks in the financial reporting system identified as part of our risk assessment.

#### Identifying significant components

- We performed a full scope audit on the financial statements of Futura Medical PLC and Futura Medical Developments Limited. We performed group level analytical procedures on the financial statements of Futura Medical Healthcare Limited.
- Our audit procedures provided coverage of 100% of each of the group and parent company's loss before tax and 100% of the group and parent company's net assets.
- The audit procedures for all components was conducted by the group audit team.

### 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 financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the 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 in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

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

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

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

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

In the light of the knowledge and understanding of the group and the parent company and 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 directors' responsibilities statement, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

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

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

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

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

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 the ISAs (UK).



## INDEPENDENT AUDITOR'S REPORT

### to the members of Futura Medical plc

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 frameworks (IFRS, the Companies Act 2006 and QCA Corporate Governance Code) and AIM rules.

In addition, we concluded that there are certain significant laws and regulations, such as Employment Law and Health and Safety regulations that may have an effect on the determination of the amounts and disclosures in the financial statements and those laws and regulations relating to health and safety, employee matters, environmental, and bribery and corruption practices.

We understood how Futura Medical PLC is complying with those legal and regulatory frameworks by making enquiries of management, those responsible for legal and compliance procedures and the company secretary. We corroborated our enquiries through our review of board minutes and correspondence received from regulatory bodies.

In assessing the potential risks of material misstatement, we obtained an understanding of:

- the entity's operations, including the nature of its objectives and strategies to understand the classes of transactions, account balances, expected financial statement disclosures and business risks that may result in risks of material misstatement;
- the applicable statutory provisions;
- the entity's control environment, including the policies and procedures implemented to comply with the requirements of its regulator, including the adequacy of the training to inform staff of the relevant legislation, rules and other regulations of the regulator, the adequacy of procedures for authorisation of transactions, internal review procedures over the entity's compliance with regulatory requirements, and procedures to ensure that possible breaches of requirements are appropriately investigated and reported.

We assessed the susceptibility of Futura Medical PLC's consolidated financial statements to material misstatement, including how fraud might occur, by making enquires of management and those charged with governance. We utilised internal and external information to corroborate these enquiries and to perform a high-level fraud risk assessment. We considered the risk of fraud to be higher through the potential for management override of controls.

Our audit procedures involved:

- evaluation of the design effectiveness and testing the operating effectiveness of controls that management has in place to prevent and detect fraud;
- journal entry testing, with a focus on material manual journals, those posted directly to cash;
- challenging assumptions and judgements made by management in its significant accounting estimates;
- assessing the extent of compliance with the relevant laws and regulations as part of our procedures on the related financial statement item.

In addition, we completed audit procedures to conclude on the compliance of disclosures in the annual report and accounts with applicable financial reporting requirements.

We assessed the appropriateness of the collective competence and capabilities of the engagement team included 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 client operates;
- understanding of the legal and regulatory requirements specific to the entity including:
  - the provisions of the applicable legislation;
  - the regulators rules and related guidance, including guidance issued by relevant authorities that interprets those rules;
  - the applicable statutory provisions.

We did not identify any matters relating to non-compliance with laws and regulation or relating to fraud.

**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.

**MARK BISHOP FCA**

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

Oxford  
13 April 2021

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

for the year ended 31 December 2020

	Notes	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Revenue	2.4	–	31,778
Research and development costs		(1,927,658)	(10,051,148)
Administrative costs		(1,000,736)	(1,144,397)
<b>Operating loss</b>	6	<b>(2,928,394)</b>	<b>(11,163,767)</b>
Finance income	8	924	22,283
<b>Loss before tax</b>		<b>(2,927,470)</b>	<b>(11,141,484)</b>
Taxation recoverable	9	519,093	2,222,194
<b>Loss for the year being total comprehensive loss attributable to owners of the Parent Company</b>		<b>(2,408,377)</b>	<b>(8,919,290)</b>
Basic and diluted loss per share (pence)	10	(0.99)	(4.36)

All amounts relate to continuing activities.

The Notes on pages 70 to 85 form part of these consolidated financial statements.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

for the year ended 31 December 2020

	Notes	Share Capital £	Share Premium £	Merger Reserve £	Warrant Reserve £	Retained Losses £	Total Equity £
<b>At 1 January 2019</b>		<b>409,167</b>	<b>49,983,860</b>	<b>1,152,165</b>	<b>-</b>	<b>(42,692,938)</b>	<b>8,852,254</b>
Total comprehensive loss for the year		-	-	-	-	(8,919,290)	(8,919,290)
Share-based payment	18	-	-	-	-	101,404	101,404
Shares issued during the year	17	154	19,130	-	-	-	19,284
Transactions with owners		154	19,130	-	-	101,404	120,688
<b>At 31 December 2019</b>		<b>409,321</b>	<b>50,002,990</b>	<b>1,152,165</b>	<b>-</b>	<b>(51,510,824)</b>	<b>53,652</b>
Total comprehensive loss for the year		-	-	-	-	(2,408,377)	(2,408,377)
Share-based payment	18	-	-	-	-	149,364	149,364
Shares issued during the year	17	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
<b>At 31 December 2020</b>		<b>491,254</b>	<b>52,814,090</b>	<b>1,152,165</b>	<b>165,868</b>	<b>(53,769,837)</b>	<b>853,540</b>

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's treated as distributable profit from the point of issue.

The Notes on pages 70 to 85 form part of these consolidated financial statements.

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

as at 31 December 2020

	Notes	As at 31 December 2020 £	As at 31 December 2019 £
<b>Assets</b>			
<b>Non-current assets</b>			
Plant and equipment	11	42,869	59,505
<b>Total non-current assets</b>		<b>42,869</b>	<b>59,505</b>
<b>Current assets</b>			
Inventories	12	–	7,780
Trade and other receivables	14	39,790	101,192
Taxation recoverable	9	518,805	2,222,194
Cash and cash equivalents	15	1,018,601	2,510,501
<b>Total current assets</b>		<b>1,577,196</b>	<b>4,841,667</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	16	(766,525)	(4,847,520)
<b>Total liabilities</b>		<b>(766,525)</b>	<b>(4,847,520)</b>
<b>Total net assets</b>		<b>853,540</b>	<b>53,652</b>
<b>Capital and reserves attributable to owners of the Parent Company</b>			
Share capital	17	491,254	409,321
Share premium		52,814,090	50,002,990
Merger reserve		1,152,165	1,152,165
Warrant reserve		165,868	–
Retained losses		(53,769,837)	(51,510,824)
<b>Total equity</b>		<b>853,540</b>	<b>53,652</b>

The consolidated financial statements were approved and authorised for issue by the Board on 13 April 2021.

The Notes on pages 70 to 85 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 2020

	Notes	Year ended 31 December 2020 £	Year ended 31 December 2019 £
<b>Cash flows from operating activities</b>			
Loss before tax		(2,927,470)	(11,141,484)
Adjustments for:			
Depreciation	11	25,008	20,704
Finance income	8	(924)	(22,283)
Share-based payment charge	18	149,364	101,404
<b>Cash flows used in operating activities before changes in working capital</b>		<b>(2,754,022)</b>	<b>(11,041,659)</b>
Decrease in inventories	12	7,780	–
Decrease in trade and other receivables		61,401	204,928
(Decrease) / increase in trade and other payables	16	(4,080,996)	2,822,004
<b>Cash used in operations</b>		<b>(6,765,837)</b>	<b>(8,014,727)</b>
Income tax received		2,222,482	1,358,480
<b>Net cash used in operating activities</b>		<b>(4,543,355)</b>	<b>(6,656,247)</b>
<b>Cash flows from investing activities</b>			
Purchase of plant and equipment	11	(8,371)	(32,736)
Interest received		924	22,283
<b>Cash used in investing activities</b>		<b>(7,447)</b>	<b>(10,453)</b>
<b>Cash flows from financing activities</b>			
Issue of ordinary shares	17	3,270,534	19,284
Expenses paid in connection with share issue		(211,632)	–
<b>Cash generated by financing activities</b>		<b>3,058,902</b>	<b>19,284</b>
<b>Decrease in cash and cash equivalents</b>		<b>(1,491,900)</b>	<b>(6,647,415)</b>
<b>Cash and cash equivalents at beginning of year</b>		<b>2,510,501</b>	<b>9,157,916</b>
<b>Cash and cash equivalents at end of year</b>	15	<b>1,018,601</b>	<b>2,510,501</b>

The Notes on pages 70 to 85 form part of these consolidated financial statements.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 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 2020.

The consolidated financial statements of the Company and the Group for the year ended 31 December 2020 were authorised for issue by the Board of Directors on 13 April 2021.

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 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

For the year ended 31 December 2020, the Group made an operating loss of £2.93 million. Cash and cash equivalents at 31 December 2020 were £1.02 million. 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 to Q1 2022. Based on this, additional funding is expected to be required to support the Group’s and the Company’s going concern status. Dependent upon the funds raised and the level of income generated from licensing activities, further funding may be required to reach profitability. The Group completed a £2.00 million fundraise which comprised of £1.50 million convertible loan notes, £0.50 million warrants and a Collaboration Agreement to commercialise MED3000 in China and South East Asia with £1.50 million received in March 2021 and £0.50 million in April 2021. The Directors have a reasonable expectation that the Group will be able to raise further financing, which could come from a variety of dilutive and non-dilutive sources, to support its ongoing activities, following the anticipated granting of the CE mark for MED3000 in Europe, expected in May 2021 following a recommendation in March 2021. The Directors also have a reasonable expectation that the Group will be able to generate significant funding through entering into strategic collaborations for the commercialisation of MED3000 and its other products in the US and Europe.

However, there can be no guarantee that the Group will be able to raise sufficient funding from existing and new investors, nor that the Group will be able to secure further strategic collaborations for its product pipeline. In the event that the Group does not successfully raise new financing, the Directors consider that the Group would be able to reduce expenditure, potentially extending the Group’s cash resources to more than 12 months from the date of signing the financial statements.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast significant doubt on the Group’s and the Company’s ability to continue as a going concern and, therefore, to continue realising its assets and discharging its liabilities in the normal course of business. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

### 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.

## 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.

Revenue recognised in the prior year related to a collaboration agreement. 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, no revenue was recognised.

### 2.5 Leased assets

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

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

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

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

The Group has elected to account for short-term leases and leases of low-value assets using the practical expedients. These leases relate to items of certain 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.



## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.11 Financial instruments (continued)

#### 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.

##### 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 (2019: £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.

### 2.12 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.



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.12 Taxation (continued)

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

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

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

### 2.13 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.

### 2.14 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 that eventually vest. There are no market vesting conditions. If the terms and conditions of share options are modified before they vest, the change in the fair value of the share options, measured immediately before and after the modification, is also charged to the Consolidated Statement of Comprehensive Income over the remaining vesting period. The proceeds received when share options are exercised, net of any directly attributable transaction costs, are credited to share capital (nominal value) and 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.

### 2.15 Finance income

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

### 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 £149,364 (2019: £101,404), 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 18.

#### 3.2 Judgements

##### 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 R&D 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 judgments 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 19.

### 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 2020 or at 31 December 2019.

At 31 December 2020 the Group had trade payables denominated in a foreign currency totalling £34,217 (31 December 2019: £101,899).

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 4. FINANCIAL RISK (CONTINUED)

### 4.1 Financial risk factors (continued)

#### 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 2020 £	31 December 2019 £
Cash at bank and in hand	644,729	2,137,599
Sterling short-term money market funds	373,872	372,902
	<b>1,018,601</b>	<b>2,510,501</b>

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 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 £1,018,601 of cash and fixed-term deposits as at 31 December 2020 (31 December 2019: £2,510,501).

## 5. SEGMENT REPORTING

The Group is focused on the development and commercialisation of MED3000 and therefore operates as one segment.

## 6. OPERATING LOSS

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
<b>Operating loss is stated after charging:</b>		
Depreciation of plant and equipment (Note 11)	25,008	20,704
Loss on disposal of plant and equipment	–	–
Inventories consumed in R&D	–	–
Short-term leases: property	116,714	117,275
Gain/(loss) on foreign exchange	18,840	8,468

## 6. OPERATING LOSS (CONTINUED)

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

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
<b>Audit services</b>		
Parent Company	43,500	35,000
Subsidiaries	7,500	7,000
<b>Tax services</b>		
Parent Company	–	–
Subsidiaries	–	–
<b>Other non-audit services</b>		
iXBRL tagging	1,000	1,000
<b>Total fees</b>	<b>52,000</b>	<b>43,000</b>

## 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	Year ended 31 December 2019
R&D staff	8	8
Finance and Administration staff	2	2
Executive Directors	3	3
	<b>13</b>	<b>13</b>

The aggregate payroll costs of these persons were as follows:

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Wages and salaries	1,598,473	1,315,760
Social security costs	154,829	181,544
Other pension and insurance benefits costs	163,910	180,342
<b>Total cash-settled emoluments</b>	<b>1,917,212</b>	<b>1,677,646</b>
Share-based payment remuneration charge	149,364	101,404
<b>Total emoluments</b>	<b>2,066,576</b>	<b>1,779,050</b>

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

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 7. STAFF NUMBERS AND COSTS (CONTINUED)

### Directors' emoluments

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Aggregate emoluments	912,209	693,353
Other pension and other benefit costs	22,968	22,506
<b>Subtotal per Remuneration Report</b>	<b>935,177</b>	<b>715,859</b>
Share-based payment remuneration charge	47,866	47,866
Employer's national insurance charge	77,222	73,811
<b>Total emoluments</b>	<b>1,060,265</b>	<b>837,536</b>

In 2020 there were no Directors whose share options were exercised under the Group share option schemes and no gain was realised (2019: £nil). In respect of the highest paid Director the realised gain was £nil (2019: £nil).

In 2020 there were no Directors (2019: 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.

Emoluments above include the following amounts in respect of the highest paid Director:

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Aggregate emoluments	306,658	235,593
Employer pension contributions and other benefits	2,652	–
<b>Subtotal per Remuneration Report</b>	<b>309,310</b>	<b>235,593</b>
Share-based payment remuneration charge	18,410	18,410
Employer's national insurance charge	32,266	31,680
<b>Total emoluments</b>	<b>359,986</b>	<b>285,683</b>

## 8. FINANCE INCOME

Interest receivable in 2020 on treasury funds was £924 (2019: £22,283).

## 9. TAXATION

### 9.1 Current tax

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
UK corporation tax credit on loss on ordinary activities	519,093	2,222,194



## 9. TAXATION (CONTINUED)

### 9.1 Current tax (continued)

The tax assessed for the year was lower than the UK corporation tax rate (2019: lower). The differences are explained below:

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Loss on ordinary activities before tax	2,927,470	11,141,484
Loss on ordinary activities at an average standard rate of corporation tax in the UK of 19% (2019: 19%)	556,220	2,116,882
Expenses not deductible for tax purposes	(6)	(304)
Unrecognised deferred tax	(37,213)	(15,701)
Unutilised tax losses	(224,744)	(841,959)
R&D expenditure credit	(1,036)	(4,969)
Loss surrendered for refund	(159,728)	(683,072)
Additional relief for R&D claims	381,186	1,630,136
UK corporation tax credit	514,679	2,201,013
Adjustment to tax charge relating to prior period	(288)	–
R&D expenditure credit re 2019	–	21,181
R&D expenditure credit re 2020	4,414	–
UK corporation tax credit reported in the Consolidated Statement of Comprehensive Income	518,805	2,222,194

The Group has tax losses of approximately £32,448,687 (2019: £31,265,826) available for offset against future taxable profits.

The corporation tax credit for the year represents research and development tax credits of £514,679 (2019: £2,201,012), arising from the surrender of losses (rather than carrying forward to future years) of £3,549,507 (2019: £15,179,395) 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.

In addition, a small claim under the large company Research and Development Expenditure Credit (RDEC) scheme resulted in a refund of £4,414 (2019: £21,181).

### 9.2 Deferred tax

Deferred tax assets amounting to £6,575,569 (2019: £5,649,021) 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. Reductions in the UK corporation tax rate from 20% to 19% (effective from 1 April 2017) were substantively enacted on 26 October 2015. The unrecognised deferred tax asset at 31 December 2020 has been calculated assuming a prevailing tax rate when the timing differences reverse of 19% (2019: 17%) and comprises:

	Year ended 31 December 2020 £	Year ended 31 December 2019 £
Depreciation differential versus capital allowances	(496)	(1,770)
Other short-term timing differences	410,814	335,600
Unutilised tax losses	6,165,251	5,315,191
	6,575,569	5,649,021

The UK corporation tax rate is expected to increase from 19% to 25% from 1 April 2023. The legislation containing this provision has not yet been substantively enacted. The unrecognised deferred tax asset at 31 December 2020 has been calculated at the rate substantively enacted at the time of preparation of the financial statements.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 10. LOSS PER SHARE

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

	2020	2019
Loss for the purposes of basic EPS and diluted EPS (£)	2,408,376	8,919,290
Weighted average of ordinary shares for purposes of basic and diluted EPS (number)	243,721,303	204,657,741
Loss per share basic and diluted (pence)	0.99	4.36

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 7,295,000 (2019: 7,255,000). 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.

## 11. PLANT AND EQUIPMENT

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

Cost	Computer Equipment £	Furniture and Fittings £	Total £
At 1 January 2019	86,602	63,285	149,887
Additions	32,736	–	32,736
<b>At 31 December 2019</b>	<b>119,338</b>	<b>63,285</b>	<b>182,623</b>
<b>Depreciation</b>			
At 1 January 2019	47,495	54,919	102,414
Charge for year	19,250	1,454	20,704
<b>At 31 December 2019</b>	<b>66,745</b>	<b>56,373</b>	<b>123,118</b>
<b>Net book value</b>			
<b>At 31 December 2019</b>	<b>52,593</b>	<b>6,912</b>	<b>59,505</b>
At 31 December 2018	39,107	8,366	47,473

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

**12. INVENTORIES**

	31 December 2020 £	31 December 2019 £
Consumable materials used for development	–	7,780

**13. 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	31 December 2020 £	31 December 2019 £
<b>Loans and receivables at amortised cost</b>		
Trade and other receivables (Note 14)	16,067	59,968
Cash and cash equivalents (Note 15)	1,018,601	2,510,501
<b>Total receivables</b>	<b>1,034,668</b>	<b>2,570,469</b>
	31 December 2020 £	31 December 2019 £
<b>Liabilities as per Consolidated Statement of Financial Position at amortised cost</b>		
Trade and other payables (Note 16)	766,525	4,847,520
<b>Total payables</b>	<b>766,525</b>	<b>4,847,520</b>

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

**14. TRADE AND OTHER RECEIVABLES**

Amounts receivable within one year:	31 December 2020 £	31 December 2019 £
Trade receivables	5,627	5,627
Other receivables	10,440	54,341
Financial assets (Note 13)	16,067	59,968
Prepayments	23,723	41,224
	<b>39,790</b>	<b>101,192</b>

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.

**15. CASH AND CASH EQUIVALENTS**

	31 December 2020 £	31 December 2019 £
Cash at bank and in hand	644,729	2,137,599
Sterling short-term money market funds	373,872	372,902
	<b>1,018,601</b>	<b>2,510,501</b>

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 16. TRADE AND OTHER PAYABLES

	31 December 2020 £	31 December 2019 £
Trade payables	182,900	2,625,359
Social security and other taxes	64,092	39,970
Deferred income	–	218,222
Accrued expenses	519,533	1,963,969
	<b>766,525</b>	<b>4,847,520</b>

The decrease in payables is reflective of the reduced activity relating to research and development activities in comparison to the prior year. Deferred income relating to the prior year was re-classified in the period as accrued expenses and released to the profit and loss as costs were recognised.

## 17. SHARE CAPITAL

	31 December 2020 Number	31 December 2019 Number	31 December 2020 £	31 December 2019 £
<b>Authorised</b>				
Ordinary shares of 0.2 pence each	500,000,000	500,000,000	1,000,000	1,000,000
<b>Allotted, called up and fully paid</b>				
Ordinary shares of 0.2 pence each	245,626,926	204,660,267	491,254	409,321

The number of issued ordinary shares as at 1 January 2019 was 204,583,439. During the year ended 31 December 2019, 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 2019	Non-Executive Director Share Award	19,284	76,828
		19,284	76,828

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 Primary Bid Offer	3,250,000	40,625,000
		3,270,534	40,966,659

## 18. SHARE OPTIONS

At 31 December 2020, 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 2020 Number	Options Exercised Number	Options Lapsed Number	Options Granted Number	At 31 December 2020 Number
1 October 2015 – 30 September 2020	71.50	620,000	–	(620,000)	–	–
1 October 2016 – 30 September 2021	51.75	580,000	–	(100,000)	–	480,000
1 October 2017 – 30 September 2022	30.00	750,000	–	(150,000)	–	600,000
1 October 2018 – 30 September 2023	57.50	960,000	–	(150,000)	–	810,000
1 October 2019 – 30 September 2024	30.50	1,140,000	–	(150,000)	–	990,000
1 October 2020 – 30 September 2025	7.50	1,390,000	–	(150,000)	–	1,240,000
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	1,400,000	–	(150,000)	–	1,250,000
1 October 2022 – 30 September 2027	15.50	–	–	–	1,500,000	1,500,000
		7,265,000	–	(1,470,000)	1,500,000	7,295,000

On 21 September 2020 share options over 1,500,000 new ordinary shares were granted to employees (including Executive Directors) at a price of 15.50p. The options have a two-year vesting period and the exercise period for these options is 1 October 2022 to 30 September 2027.

The share options outstanding at 31 December 2020 represented 2.97% of the issued share capital as at that date (2019: 3.54%) and would generate additional funds of £1,939,700 (2019: £2,433,900) if fully exercised. The weighted average remaining life of the share options outstanding at 31 December 2020 was 56 months (2019: 51 months) with a weighted average remaining exercise price of 29.04 pence (2019: 33.55 pence).

The share options exercisable at 31 December 2020 totalled 4,545,000 (2019: 3,850,000) with an average exercise price of 26.04 pence (2019: 48.48 pence) and would have generated additional funds of £1,319,700 (2019: £1,766,650) if fully exercised.

The Group's share option scheme rules apply to 6,720,000 of the share options outstanding at 31 December 2020 (31 December 2019: 6,550,000) 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 575,000 share options outstanding to advisers at 31 December 2020 (31 December 2019: 705,000).

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.

### Share-based payments

Inputs to share option pricing model	31 December 2020	31 December 2019
Grant date	21 September	17 September
Number of shares under option	1,500,000	1,390,000
Share price as at date of grant	14.72 pence	30.70 pence
Option exercise price	15.5 pence	31.00 pence
Expected life of options: based on previous exercise history	3 years	3 years
Expected volatility: based on median fluctuations over 3 years	104.96%	82.70%
Dividend yield: no dividends assumed	0%	0%
Risk-free rate: yield on 3-year treasury stock as at date of grant	0.05% p.a.	0.48% p.a.



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

for the year ended 31 December 2020

## 18. SHARE OPTIONS (CONTINUED)

Outputs generated from share option pricing model	31 December 2020	31 December 2019
Fair value per share under option	9.24p	16.19p
Total expected charge over the vesting period	£138,600	£225,041

Recognised in Consolidated Statement of Comprehensive Income	31 December 2020 £	31 December 2019 £
The share-based remuneration charge comprises:		
Share-based payments – employees	19,104	32,019
Share-based payments – consultants	–	–
Share-based payments	19,104	32,019

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

	31 December 2020 £	31 December 2019 £
Group equity-settled share-based payment expense	149,364	101,404

## 19. WARRANT INSTRUMENT

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:

Inputs to warrant pricing model	31 December 2020	31 December 2019
Grant date	21 January	–
Number of warrants	10,937,500	–
Share price as at date of grant	12.75 pence	–
Warrant conversion price	40 pence	–
Expected life of warrants:	5 years	–
Expected volatility: based on median fluctuations over 3 years	81.56%	–
Dividend yield: no dividends assumed	0%	–
Risk-free rate: yield on 3-year treasury stock as at date of grant	0.44% p.a.	–

## 20. PENSION COSTS

The pension charge represents contributions payable by the Group to independently administered funds which during the year ended 31 December 2020 amounted to £128,161 (2019: £164,458). Pension contributions payable in arrears at 31 December 2020, included in accrued expenses at the relevant Consolidated Statement of Financial Position date, totalled £18,948.36 (2019: £10,225).

## 21. COMMITMENTS

At 31 December 2020 the Group had operating lease commitments in respect of property leases cancellable on one month's notice of £9,802 (2019: £9,802).

## 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.

## 23. POST PERIOD EVENTS

The Group concluded a funding transaction in March 2021. The transaction comprised of £1.50 million of convertible loan notes priced at 20 pence per ordinary share, £0.50 million of warrants with an exercise price of 22 pence and the Group entered also into a Collaboration Agreement to develop and commercialise MED3000 in China and South East Asia.

### Convertible loan notes

£1.50 million cash was received in March 2021 relating to convertible loan notes which expire after three years but a mandatory conversion will trigger once EU approval has been granted and Futura Medical Plc share price remains at 30 pence or above for at least one month. Conversion of the loan notes will result in 7,500,000 ordinary shares issued upon conversion.

### Warrants

Futura issued warrants to purchase £0.50 million of Futura Medical plc ordinary shares. The warrants expire after four years from date of issue and they have an exercise price of 22 pence. The warrants were exercised in April 2021 and 2,272,727 ordinary shares will be issued.

### Collaboration Agreement

The Group also entered into a Collaboration Agreement to develop and commercialise MED3000 in China and South East Asia. Futura has granted a licence to MED3000's intellectual property and the counter-party will fund the costs of development. Futura will retain a 50% profit share.

## PARENT COMPANY BALANCE SHEET

as at 31 December 2020

Company number: 04206001

	Notes	As at 31 December 2020 £	As at 31 December 2019 £
<b>Fixed assets</b>			
Investment	2	53,616,120	50,178,526
<b>Current assets</b>			
Debtors – due within one year	3	9,934	13,267
Total debtors		9,934	13,267
Cash at bank and in hand		410,417	1,099,413
		420,351	1,112,680
<b>Creditors: amounts falling due within one year</b>	4	(123,127)	(200,158)
<b>Net current assets</b>		297,224	912,522
<b>Net assets</b>		53,913,344	51,091,048
<b>Capital and reserves</b>			
Called up share capital	5	491,254	409,321
Share premium account		52,814,090	50,002,990
Warrant reserve		165,868	–
Profit and loss account		442,132	678,737
<b>Shareholders' funds</b>		53,913,344	51,091,048

The loss in respect of the Company for the year was £385,969 (2019: £514,098). The Parent Company financial statements were approved and authorised for issue by the Board on 13 April 2021.

The Notes on pages 88 to 90 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 2020

	Note	Share Capital £	Share Premium £	Warrant Reserve £	Profit and Loss Account £	Total Equity £
<b>At 1 January 2019</b>		<b>409,167</b>	<b>49,983,860</b>	<b>–</b>	<b>1,091,431</b>	<b>51,484,458</b>
Total comprehensive loss for the year		–	–	–	(514,098)	(514,098)
Share-based payment		–	–	–	101,404	101,404
Issue of shares	5	154	19,130	–	–	19,284
<b>At 31 December 2019</b>		<b>409,321</b>	<b>50,002,990</b>	<b>–</b>	<b>678,737</b>	<b>51,091,048</b>
Total comprehensive loss for the year		–	–	–	(385,969)	(385,969)
Share-based payment		–	–	–	149,364	149,364
Issue of shares	5	81,933	2,811,100	165,868	–	3,058,901
<b>At 31 December 2020</b>		<b>491,254</b>	<b>52,814,090</b>	<b>165,868</b>	<b>442,132</b>	<b>53,913,344</b>

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’s 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 88 to 90 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 £385,969 (2019: £514,098). 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 (refer to Note 3). The results of the subsidiary are included in the consolidated financial statements. The Company capitalises intercompany balances with its subsidiaries at each month-end (creating an investment in subsidiaries) up to the point where it believes the subsidiary is in a position to repay any balances within the next 12 months. Capitalised balances are reviewed for impairment annually. It was concluded that there was no impairment required. This conclusion requires judgement and if regulatory approval of MED3000 is rejected, this could result in material impairment.

	£
At 1 January 2019	43,023,474
Additions in the year	7,155,052
At 31 December 2019	50,178,526
Additions in the year	3,437,594
<b>At 31 December 2020</b>	<b>53,616,120</b>

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 2020 £	31 December 2019 £
Amounts receivable within one year: prepayments	9,934	13,267

## NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS

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

	31 December 2020 £	31 December 2019 £
Trade creditors	66,212	107,299
Accruals	56,915	92,859
	<b>123,127</b>	<b>200,158</b>

### 5. CALLED UP SHARE CAPITAL

	31 December 2020 Number	31 December 2019 Number	31 December 2020 £	31 December 2019 £
<b>Authorised</b>				
Ordinary shares of 0.2 pence each	500,000,000	500,000,000	1,000,000	1,000,000
<b>Allotted, called up and fully paid</b>				
Ordinary shares of 0.2 pence each	245,626,926	204,660,267	491,254	409,321

Details of shares issued by the Company in the year and details of share options outstanding are given in Notes 17 and 18 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	Non-Executive Chairman
James Barder	Chief Executive Officer
Angela Hildreth	Finance Director and Chief Operating Officer
Ken James	Executive Director
Jonathan Freeman	Non-Executive Director

### AUDIT COMMITTEE

Jonathan Freeman  
John Clarke

### REMUNERATION COMMITTEE

Jonathan Freeman  
John Clarke

### NOMINATIONS COMMITTEE

John Clarke  
Jonathan Freeman

### SECRETARY AND REGISTERED OFFICE

Angela Hildreth  
Futura Medical plc  
Surrey Technology Centre  
40 Occam Road  
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Surrey  
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Berkshire  
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### REGISTRAR

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### PRINCIPAL BANKER

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