

## **Futura Medical plc**

("Futura" or "the Company")

### **Interim Results for the Six Months ended 30 June 2019**

Futura Medical plc (AIM: FUM) ("Futura" or the "Company"), a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® drug delivery technology currently focused on sexual health and pain, is pleased to announce its interim results for the six months ended 30 June 2019.

#### **Highlights**

##### **MED2005 – Topical glyceryl trinitrate (GTN) formulation for erectile dysfunction**

- Patient recruitment completed in June 2019 for the MED2005 first European Phase 3 study "FM57". This study is on track to deliver headline efficacy and safety data by the end of 2019. Patient recruitment was completed in June 2019 and at the end of August over 500 patients had completed the 12 week double-blind phase of the study with 80% of these patients having elected to continue into the open label extension to study long term safety of the highest dose.
- Planning for a second, confirmatory Phase 3 study for MED2005 is underway.
- Positive data to support safety in sexual partners provided at the European Society of Sexual Medicine (ESSM) congress in February 2019, including a review of safety data from the Phase 2a study, pharmacokinetic study and in-vitro impedance data.
- Second advisory panel held at ESSM in Slovenia in February 2019 with prominent European key opinion leaders (KOLs) to review the data and discuss the on-going development and educational programme. As with US KOLs, their reaction to the therapeutic potential for MED2005 in erectile dysfunction and its areas of differentiation as well as the ongoing clinical programme was highly positive reflecting the limited amount of innovation in the sector for over ten years.

##### **TPR100 – Topical non-steroidal anti-inflammatory for the pain and inflammation associated with sprains, strains and bruises and soft tissue rheumatism**

- UK partner Thornton & Ross (a subsidiary of STADA AG) received feedback from UK Medicines and Healthcare products Regulatory Agency (MHRA) in February 2019 requiring additional laboratory work to be conducted to support the UK filing. This work is progressing, and we expect to respond in Q1 2020 within the timelines agreed with the MHRA.
- Ongoing commercial discussions with several potential distribution partners for other territories. Any further licensing deals are expected to be after UK regulatory approval.

##### **CBD100 - Joint Venture Collaboration on optimised topical delivery of Cannabidiol**

- Joint venture collaboration with CBDerma Technology Limited to explore the application of DermaSys® for optimised delivery of Cannabidiol through the skin to explore a number of disease states including pain relief. The initial joint venture development costs are expected to be in the region of \$1 million. Any Intellectual Property will be jointly owned.

### **Financial highlights**

- £4.46 million net loss in the period (30 June 2018: net loss £1.95 million).
- Cash resources of £5.63 million at 30 June 2019 (30 June 2018: £6.03 million).
- R&D tax credits of £1.36 million for year ending 2018 received in August (Year ending 2017: £0.94 million)

**James Barder, Chief Executive of Futura, commented:** “We continue to make good progress in the development and commercialisation of our pipeline of product opportunities. We are pleased to have completed recruitment for the double-blind, clinical efficacy of the first European Phase 3 study of MED2005. Most patients have elected to continue into the open-label, Phase 3, safety stage in which all patients are on the highest dose of MED2005. We look forward to Phase 3 headline data by the end of the year. Engagement with eminent experts in the field of erectile dysfunction continues in both Europe and the US to increase awareness as well as with potential commercial partners in advance of Phase 3 results which remain our key priority to deliver on by the end of 2019.”

### **Analyst meeting and webcast**

The Executive Team will host a presentation at 10am (BST), 11 September 2019, for analysts at the office of Liberum Capital at 25 Ropemaker Street, London, EC2Y 9LY. Analysts wishing to attend the presentation should register their interest by emailing [futuramedical@optimumcomms.com](mailto:futuramedical@optimumcomms.com).

Following the results meeting, a webcast of the presentation will also be made available within the [Investor Centre](#) section of the Futura company website at [www.futuramedical.com](http://www.futuramedical.com).

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## **Notes to editors:**

### **About Futura Medical plc**

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

The first European Phase 3 study for MED2005, referred to as “FM57”, is a 1,000 patient, dose-ranging, multi-centre, randomised, double blind, placebo-controlled, home use, parallel group study of MED2005 0.2%, 0.4% and 0.6% Glyceryl Trinitrate for the treatment of erectile dysfunction with a 450 patient open label extension. FM57 is progressing on track, with headline data expected by the end of 2019.

Futura is based in Guildford, Surrey, and its shares trade on the AIM market of the London Stock Exchange.  
[www.futuramedical.com](http://www.futuramedical.com)

## **Operational Review - “Building for the future”**

As an innovative, specialist R&D company, Futura’s strategy is to leverage its DermaSys® transdermal delivery technology to bring innovative products to market in sexual health and pain, bringing new treatment options to patients particularly in areas of significant unmet need.

### **MED2005 – Topical gel for erectile dysfunction (“ED”)**

Futura’s lead product MED2005 is a topical glyceryl trinitrate (GTN) gel for the treatment of erectile dysfunction (ED). MED2005 has the potential to be a highly differentiated therapy, especially for mild to moderate ED. In a Phase 2a study, MED2005 was shown to have a fast onset of action (5-10 minutes) and rapid clearance. MED2005 has the potential to be the fastest-acting ED treatment available.

Erectile dysfunction disrupts the lives of at least 1 in 5 men globally<sup>1</sup>, affecting the sexual and emotional health of around 27 million men and their partners in the USA alone. There has been little innovation in ED treatments for over ten years and many patients continue to suffer dissatisfaction with existing treatments especially those looking for a fast-acting treatment that can form part of sexual foreplay or those contraindicated from using existing therapies<sup>2</sup>.

Recent focus group research conducted by Futura in the UK on pre and post-menopausal women with partners with erectile dysfunction showed strong interest in MED2005 and its unique attributes. In particular it highlighted the perceived benefit of MED2005 providing a shared sexual experience with the potential to take the responsibility of treatment away from their male partner alone towards a solution that is embraced by the couple together. KOLs have consistently said treating the couple is more effective than treating the individual.

With an independently assessed market potential of over \$1 billion as a prescription treatment and subsequently over the counter (OTC) treatment<sup>3</sup>, MED2005 is Futura’s lead asset and a key value creation opportunity.

### ***Phase 3 clinical programme progressing well***

#### ***“FM57” – First, European Phase 3***

MED2005’s first Phase 3 study, “FM57” completed patient recruitment in June 2019. The 1,000 patient study includes approximately 60 centres across Central and Eastern Europe. Futura remains on track to deliver first Phase 3 headline data by the end of 2019.

This Phase 3 study is a dose ranging, randomised, double blind, placebo controlled, home use, parallel group clinical trial and compares the efficacy of 0.2%, 0.4% and 0.6% GTN doses of MED2005 in mild, moderate and severe ED patients.

Following positive Phase 2a “FM53” data, we have confidence that the higher doses of 0.4% and 0.6% being studied in addition to the 0.2% dose will show improved efficacy across patients with mild, mild to moderate and moderate ED - which represent the large majority of ED sufferers throughout the world and the largest commercial opportunity. Severe ED patients, who often have the most medical complications as well as being

the oldest men, are a difficult patient cohort to treat. This is further evidenced by the limited success of the existing ED treatments in this cohort. We therefore remain cautious over the potential benefit MED2005 will bring to severe patients. As the first Phase 3 includes patients of all ED severities, if reduced efficacy in severe ED patients occurs, it is not expected to compromise the overall success of the study.

KOLs in both US and EU have expressed strong interest in a locally acting, fast and safe new treatment for ED that particularly targets those younger patients with mild and mild to moderate ED where frequency of intercourse is generally high compared to those patients with moderate to severe ED.

As part of the Phase 3 programme, Futura is required by regulators to run an open label extension study for safety. After patients complete their 4-month trial period, they are invited to enter the open label extension study ("OLE") to assess safety at the highest dose (0.6% GTN) up to the required number of 450 patients. Of these patients 300 are to continue treatment for a further 6 months and 150 patients for a further 12 months. At the end of August 500 patients had completed the 12 week double-blind phase of the study with 80% of these patients having elected to continue into the open label extension to study long term safety of the highest dose. This OLE is a normal requirement of regulators for pharmaceutical products to provide additional reassurance on safety for longer term use of MED2005.

### ***"FM59" – Second, confirmatory Phase 3***

We anticipate patient enrolment to commence for "FM59", a second, confirmatory Phase 3 study for MED2005 in H1 2020.

This study will incorporate a US patient cohort and we will be shortly filing protocols and an Investigational New Drug Application (IND) in the US. The protocols for this study will be the same as for "FM57" initially but will be informed by the receipt and analysis of the first Phase 3 data and adapted accordingly, if necessary, via regulatory amendments. The second Phase 3 will be a placebo controlled, parallel group study and will compare the efficacy of two GTN doses of MED2005, shown to be optimal in the first Phase 3 trial, in a smaller patient cohort of around 700 patients. The Company is currently undertaking pre-recruitment start-up activities in order to commence patient enrolment in H1 2020.

Completion of the second, confirmatory Phase 3 study, expected by the end of 2020, is subject to funding and positive results from "FM57", the first European Phase 3 trial. Any financing is expected to depend on the strength of the results in FM57. In anticipation of this, the Board is therefore exploring both non-dilutory and dilutory funding options and intends to place the Company in a position of strength to continue capitalising on product development and for negotiating any out-licensing agreements for MED2005.

It is usual for two Phase 3 studies to be required for regulatory filing. However, depending on data from the first European Phase 3 study, Futura may explore filing MED2005 with regulatory bodies in Europe with one Phase 3 study which could occur during H2 2020. The US FDA has been clear that two studies are required, and US filing will await results from the second Phase 3 study.

Futura held a R&D analyst event in London in February 2019 including a presentation from Professor David Ralph, a world leading expert in erectile dysfunction and male infertility and Chair of the Futura Medical

European Advisory Panel. These activities and events organised by Futura are continuing to increase the awareness and credibility of the potential innovation that MED2005 brings within the treatment arena of ED to both the medical and pharmaceutical communities. A second US advisory board meeting has been arranged for October 2019 at the Sexual Medicine Society of North America Conference.

Discussions continue with a number of interested commercial partners for the out-licensing of MED2005 although the Company's main focus is to deliver Phase 3 headline data by the end of 2019 and prepare for the second smaller Phase 3 which is critical for US regulatory approval in order to bring MED2005's novel benefits to ED patients through the EU and US as soon as possible.

We believe MED2005 has the required efficacy, speed of onset and favourable safety profile consistent with use as a prescription therapy as well as the potential to be an over-the-counter therapy.

### ***MED2005 Intellectual Property***

MED2005's current patent protection runs until August 2028 in the USA and August 2025 in Europe. In August 2018 Futura filed a Patent Co-operation Treaty (PCT) patent filing which is expected to extend patent life in many geographies to 2038. The PCT filing will be moving into the National filing phase in Q1 2020 in line with standard processes. This phase sets out specific, nominated countries under the Patent Co-operation Treaty which will adhere to the 2018 priority date through to 2037.

The EU also can provide up to ten year's data exclusivity and US up to three years from the date of regulatory approval subject to EU and FDA guidelines.

### **TPR100 – Topical gel for pain relief**

TPR100 is a topical non-steroidal anti-inflammatory for the treatment of pain and inflammation associated with sprains, strains, bruises and soft tissue rheumatism.

TPR100 is partnered for manufacturing and distribution in the UK with Thornton & Ross, one of the UK's largest consumer healthcare companies and a subsidiary of STADA AG. In February 2019, the UK Medicines and Healthcare products Regulatory Agency (MHRA) responded to Thornton & Ross's marketing authorisation application filed in July 2018, raising a number of questions requiring additional laboratory work specifically around the permeation characteristics of TPR100 to be conducted. This work is progressing, and we expect Thornton & Ross to respond by the end of February 2020 within the timelines agreed with the MHRA.

The Company has received expressions of interest from a number of parties to enable Futura to expand the geographical reach of TPR100. Futura is awaiting regulatory authorisation in the UK before progressing further with these discussions.

## **CBD100 - Joint Venture Collaboration on optimised topical delivery of Cannabidiol**

A joint venture collaboration has been signed with CBDerma Technology Limited to explore the application of Futura's advanced proprietary transdermal drug delivery technology, DermaSys® for delivery of Cannabidiol. All Intellectual Property will be owned jointly by the Company and CBDerma Technology Limited.

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 advisors have extensive knowledge, expertise and investments in plant derived product manufacturing. 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.

Initial development costs are expected to be in the region of US\$ 1 million and will cover all development costs incurred by the Company during the next 15 months in order to develop and optimise a DermaSys®-cannabidiol formulation as well as 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. The Company does not expect this project's initial development to have any material impact on cashflow as Futura's financial share of the project will be delivered from its expertise and existing internal resources.

DermaSys® provides rapid and targeted local delivery of active pharmaceutical ingredients at therapeutic levels through the skin to the required site of action with a high level of safety. It is a versatile and bespoke technology that can be tailored to suit the specific active compound being used and the therapeutic indication. Each product is formulated to maximise its benefits for patients and consumers and can be developed for the prescription and consumer healthcare markets as appropriate.

## **Financial Review**

### **Research and Development Costs**

Research and Development costs for the six months ended 30 June 2019 were £4.74 million, compared to £1.65 million for the six months ended 30 June 2018. The increase of £3 million is attributable to the FM57 Phase 3 study which is running on time, within budget and expected to provide headline data in December 2019.

### **Administrative Costs**

Administrative costs were £0.53 million for the six months ended 30 June 2019 compared to £0.86 million for the six months ended 30 June 2018 and were reflective of the Company's strategy to keep central costs lean and focus cash resources on delivering the R&D programme.

### **Going Concern**

At the period end the Group held £5.63 million of cash with a further £1.36 million of R&D tax credit refund received after the period end, in August 2019. As has been previously discussed, the cash currently held by the Group will not be sufficient to complete the second Phase 3 study (FM59) which the Group intends to commence during 2020, assuming that the results of FM57 are positive. The Board is therefore exploring a

number of funding options including non-dilutory and dilutory options and believe that the results of the FM57 trial will have a major impact on these funding options and the costs associated with them. Whilst there can be no guarantee that any of these opportunities will be successfully concluded, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

### **Taxation**

The tax credit of £0.8 million (2018: £0.6m) is an accrual for the expected R&D tax credit receivable for the six months ended 30 June 2019.

### **Post Period Events**

The R&D tax credit relating to 2018 claim of £1.36 million was received in August 2019.

### **Outlook**

Futura now has the potential for a significant value inflection driven by MED2005 late stage clinical development. We look forward to headline data from the first Phase 3 study towards the end of 2019. We are excited to be moving closer to bringing an innovative, highly differentiated ED product to market that could help the many ED patients whose needs are not met by current treatments. In parallel we are managing the Company's resources prudently whilst planning and building for the future to further leverage our DermaSys® technology and products.

### *References*

*1 EMEA, Withdrawal assessment report for Viagra, 2008*

*2 50% of men discontinue treatment on PDE5s, reference Carvalheira J Sex Med. 2012 Sep;9(9):2361-9.*

*Research from Decision Resources Group and Cello Health Consulting show that many patients are dissatisfied with their treatment. In the research from Cello, physicians stated that the main reason they see their patients switch to MED2005 is the speed of onset.*

*3 Based on external market assessments from market research conducted by Cello Health Consulting as a prescription product and Ipsos Group as an over the counter product.*

# Consolidated Statement of Comprehensive loss

For the six months ended 30 June 2019

		Unaudited 6 months ended 30 June 2019	Unaudited 6 months ended 30 June 2018	Audited year ended 31 December 2018
	Notes	£	£	£
<b>Revenue</b>		-	-	-
Research and development costs		<b>(4,739,965)</b>	<b>(1,652,536)</b>	(6,038,941)
Administrative costs		<b>(534,545)</b>	<b>(866,132)</b>	(1,227,547)
<b>Operating loss</b>		<b>(5,274,510)</b>	<b>(2,518,668)</b>	(7,266,488)
Finance income		<b>13,395</b>	<b>9,429</b>	27,576
<b>Loss before tax</b>		<b>(5,261,115)</b>	<b>(2,509,239)</b>	(7,238,912)
Taxation	9	<b>800,000</b>	<b>558,557</b>	1,358,336
<b>Total comprehensive loss for the period attributable to owners of the parent company</b>		<b>(4,461,115)</b>	<b>(1,950,682)</b>	(5,880,576)
Loss per share (pence)	5	<b>(2.18p)</b>	<b>(1.61p)</b>	(4.46p)

# Consolidated Statement of Changes in Equity

For the six months ended 30 June 2019

	Share Capital £	Share Premium £	Merger Reserve £	Retained Losses £	Total Equity £
<b>At 1 January 2018 - audited</b>	<b>241,392</b>	<b>44,671,396</b>	<b>1,152,165</b>	<b>(36,959,195)</b>	<b>9,105,758</b>
Total comprehensive loss for the period	-	-	-	(1,950,682)	(1,950,682)
Share-based payment	-	-	-	103,464	103,464
Shares issued during the period	620	92,380	-	-	93,000
<b>At 30 June 2018 - unaudited</b>	<b>242,012</b>	<b>44,763,776</b>	<b>1,152,165</b>	<b>(38,806,413)</b>	<b>7,351,540</b>
Total comprehensive loss for the period	-	-	-	(3,929,894)	(3,929,894)
Share-based payment	-	-	-	43,369	43,369
Shares issued during the period	167,155	5,220,084	-	-	5,387,239
<b>At 31 December 2018 - audited</b>	<b>409,167</b>	<b>49,983,860</b>	<b>1,152,165</b>	<b>(42,692,938)</b>	<b>8,852,254</b>
Total comprehensive loss for the period	-	-	-	(4,461,115)	(4,461,115)
Share-based payment	-	-	-	41,724	41,724
Shares issued during the period	154	19,130	-	-	19,284
<b>At 30 June 2019 - unaudited</b>	<b>409,321</b>	<b>50,002,990</b>	<b>1,152,165</b>	<b>(47,112,329)</b>	<b>4,452,147</b>

# Consolidated Statement of Financial Position

At 30 June 2019

	Notes	Unaudited 30 June 2019 £	Unaudited 30 June 2018 £	Audited 31 December 2018 £
<b>Assets</b>				
<b>Non-current assets</b>				
Plant and equipment		71,800	55,681	47,473
<b>Total non-current assets</b>		<b>71,800</b>	<b>55,681</b>	47,473
<b>Current assets</b>				
Inventories		7,780	70,413	7,780
Trade and other receivables	6	122,887	152,049	306,408
Current tax asset		2,158,192	1,485,803	1,358,192
Cash and cash equivalents	7	5,626,792	6,025,174	9,157,916
<b>Total current assets</b>		<b>7,915,651</b>	<b>7,733,439</b>	10,830,296
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		(3,535,304)	(437,580)	(2,025,515)
<b>Total liabilities</b>		<b>(3,535,304)</b>	<b>(437,580)</b>	(2,025,515)
<b>Total net assets</b>		<b>4,452,147</b>	<b>7,351,540</b>	8,852,254
<b>Capital and reserves attributable to owners of the parent company</b>				
Share capital		409,321	242,012	409,167
Share premium		50,002,990	44,763,776	49,983,860
Merger reserve		1,152,165	1,152,165	1,152,165
Retained losses		(47,112,329)	(38,806,413)	(42,692,938)
<b>Total equity</b>		<b>4,452,147</b>	<b>7,351,540</b>	8,852,254

# Consolidated Statement of Cash Flows

For the six months ended 30 June 2019

	Unaudited 6 months ended 30 June 2019 £	Unaudited 6 months ended 30 June 2018 £	Audited year ended 31 December 2018 £
<b>Cash flows from operating activities</b>			
Loss before tax	(5,261,115)	(2,509,239)	(7,238,912)
Adjustments for:			
Depreciation	7,860	9,935	19,850
Loss on disposal of fixed assets			703
Finance income	(13,395)	(9,429)	(27,576)
Share-based payment charge	41,724	103,464	146,833
<b>Cash flows from operating activities before changes in working capital</b>			
	<b>(5,224,926)</b>	<b>(2,405,269)</b>	<b>(7,099,125)</b>
Decrease in inventories	-	-	62,633
(Increase) / decrease in trade and other receivables	183,522	29,027	(125,332)
(Decrease) / increase in trade and other payables	1,509,788	(61,561)	1,526,375
<b>Cash used in operations</b>	<b>(3,531,617)</b>	<b>(2,437,803)</b>	<b>(5,635,426)</b>
Income tax received	-	-	927,391
<b>Net cash used in operating activities</b>	<b>(3,531,617)</b>	<b>(2,437,803)</b>	<b>(4,708,035)</b>
<b>Cash flows from investing activities</b>			
Purchase of plant and equipment	(32,186)	(2,099)	(4,510)
Interest received	13,395	9,429	27,576
<b>Cash (absorbed) / generated by investing activities</b>	<b>(18,791)</b>	<b>7,330</b>	<b>(23,066)</b>
<b>Cash flows from financing activities</b>			
Issue of ordinary shares	19,284	93,000	5,943,421
Expenses paid in connection with share issues	-	-	(463,182)
<b>Cash generated by financing activities</b>	<b>19,284</b>	<b>93,000</b>	<b>5,480,239</b>
<b>(Decrease) / increase in cash and cash equivalents</b>	<b>(3,531,124)</b>	<b>(2,337,472)</b>	<b>795,270</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>9,157,916</b>	<b>8,362,646</b>	<b>8,362,646</b>
<b>Cash and cash equivalents at end of period</b>	<b>5,626,792</b>	<b>6,025,174</b>	<b>9,157,916</b>

## **Notes to the Consolidated Interim Financial Statements**

For the six months ended 30 June 2019

### **1. Corporate Information**

The interim condensed consolidated financial statements of Futura Medical plc and its subsidiaries (the “Group”) for the six months ended 30 June, 2019 were authorised for issue in accordance with a resolution of the Directors on 10th September, 2019. 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.

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

### **2. Accounting policies**

The accounting policies applied in these interim statements are consistent with those of the annual financial statements for the year end 31 December 2018, as described in those financial statements except for the new accounting policies described in accounting developments below.

These condensed interim consolidated financial statements for the six months ended 30 June 2019 and for the six months ended 30 June 2018 do not constitute statutory accounts within the meaning of section 434(3) of the Companies Act 2006 and are unaudited.

The Group’s financial information for the year ended 31 December 2018 has been extracted from the financial statements of the statutory accounts (“Annual Report”) of Futura Medical plc, which were prepared in accordance with International Financial Reporting Standards (“IFRSs”) as adopted by the European Union and International Financial Reporting Interpretations Committee (“IFRIC”) interpretations that were applicable for the year ended 31 December 2018 and does not constitute the full statutory accounts for that period. The Annual Report for 2018 has been filed with the Registrar of Companies. The Independent Auditor’s Report on those financial statements was unqualified and did not contain a statement under Section 498 (2) or (3) of the Companies Act 2006; though it did include a reference to a matter to which the auditor drew attention by way of emphasis without qualifying their report in relation to going concern. It does not comply with IAS 34 Interim financial reporting, as is permissible under the rules of AIM.

#### **Accounting developments**

The Directors have considered all new standards, amendments to standards and interpretations which are mandatory for the first time for the financial year beginning 1 January 2019. From 1 January 2019 the Company adopted *IFRS 16 Leases* and concluded that the adoption of IFRS 16 does not have a material impact on the Group’s consolidated statements and requires no transitional adjustments to be made.

### **3. Critical accounting judgements, assumptions and estimates**

The preparation of the interim condensed 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 period.

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.

### **Going concern**

The Group has reported a loss after tax for the six months ended 30 June 2019 of £4.46 million (six months ended 30 June 2018: £1.95 million, year ended 31 December 2018: £5.88 million). The Group holds cash balances of £5.63 million at 30 June 2019 (30 June 2018: £6.03 million, 31 December 2018: £9.16 million)

The Directors have prepared a detailed forecast to 31 December 2021 based on current plans. The forecast assumes both committed costs and future planned discretionary spend and the Directors consider that they will have sufficient cash resources to settle all committed costs and discretionary costs for at least 12 months from the date of approval of these financial statements. The forecasts also assume that the group will be able to raise additional sources of finance to fund future expenditure if the results of the MED2005 trial are positive.

It should be noted that the forecasts do not include any cash receipts from future MED2005 out-licensing agreements or other forms of funding that the Directors are actively considering, and which the Directors believe, from previous and ongoing discussions will result in material cashflow into the business during the detailed forecast period to 31 December 2021.

The Directors continue to monitor the levels of discretionary spend and have the ability to delay certain costs, such as Research and Development expenditure, in the event of unforeseen cash constraints or delayed cash receipts.

The Directors have also considered a scenario where the Phase 3 results of the MED2005 trial are not successful, although this scenario is considered to be highly unlikely. In this scenario the Directors will have sufficient cash to meet and settle all the committed expenditure and have sufficient cash to re-align their business strategy and continue investment in other products within their pipeline. The cash balances will be sufficient to cover at least 12 months from the date of signing the financial statements.

The Directors, having reviewed the Group's and Company's budgets and plans, taking account of reasonably possible changes in trading performance, have a reasonable expectation that the Group and the Company have adequate resources to continue in operational existence for the foreseeable future (being at least 12 months from the date of approval of these financial statements) and that it is therefore appropriate to continue to adopt the going concern basis in preparing the financial statements.

Based on the above, the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, they acknowledge there exists a material uncertainty over the Group's ability to access additional sources of finance which may be dependent upon the outcome of the MED2005

trial - that may cast significant doubt on the Group's and 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.

### 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, the inputs of which require the use of estimation.

### 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.

## 4. Segment reporting

There was no revenue reported in the six months ended 30 June 2019 or in the comparator period therefore, there is no segmental information to report in respect of turnover.

## 5. Loss per share (pence)

The calculation of the loss per share is based on a loss of £4,461,115 (six months ended 30 June 2018: loss of £1,950,682; year ended 31 December 2018: loss of £5,880,576) and on a weighted average number of shares in issue of 204,655,173 (six months ended 30 June 2018: 120,959,395; year ended 31 December 2018: 131,936,761). The loss attributable to equity holders of the Company for the purpose of calculating the fully diluted loss per share is identical to that used for calculating the basic loss per share. The exercise of share options, or the issue of shares under the long-term incentive scheme, would have the effect of reducing the loss per share and is therefore anti-dilutive under the terms of IAS 33 'Earnings per Share'.

## 6. Trade and other receivables

	<b>Unaudited 30 June 2019 £</b>	Unaudited 30 June 2018 £	Audited 31 December 2018 £
Amounts receivable within one year:			
Trade receivables	<b>627</b>	<b>627</b>	627
Other receivables	<b>63,604</b>	<b>23,253</b>	247,799
Prepayments and accrued income	<b>58,656</b>	<b>128,168</b>	57,982
	<b>122,887</b>	<b>152,049</b>	306,408

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.

**7. Cash and cash equivalents**

	<b>Unaudited 30 June 2019 £</b>	Unaudited 30 June 2018 £	Audited 31 December 2018 £
Cash at bank and in hand	<b>2,162,364</b>	<b>186,097</b>	5,706,519
Sterling fixed rate short-term deposits	<b>3,464,428</b>	<b>5,839,077</b>	3,451,397
	<b>5,626,792</b>	<b>6,025,174</b>	9,157,916

**8. Related party transactions**

Related parties, as defined by IAS 24 'Related Party Disclosures', are the wholly owned subsidiary companies: Futura Medical Developments Limited and 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.

**9. Taxation**

The Group's tax credit in the six months ended 30 June 2019 was £0.8 million (six months ended 30 June 2018: £0.55m, year ended 31 December: £1.36 million). The current period tax credit relates to anticipated R&D tax credits in respect of claims not yet submitted for the 2019 financial year.

**10. Subsequent events**

In August 2019, the Group received the 2018 R&D tax credit of £1.36m.

**Company number**

04206001

**Directors**

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

**Audit committee**

Jonathan Freeman  
John Clarke

**Remuneration committee**

Jonathan Freeman  
John Clarke

**Nominations committee**

John Clarke  
Jonathan Freeman

**Secretary and registered office**

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