



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

### **Interim Results for the six months 30 June 2017**

Futura Medical plc (AIM: FUM), the innovative healthcare company focused on advanced transdermal technology, is pleased to announce its interim results for the six months ended 30 June 2017.

#### **Highlights**

##### **MED2002: Eroxon® - Treatment for erectile dysfunction ("ED")**

- Key meetings with US and UK regulators in H1 2017 on the further clinical development of MED2002 following breakthrough clinical results in H2 2016
- Pharmacokinetic study to begin in Q4 2017 with the results informing a large-scale Phase III study to begin in H1 2018
- Out-licensing discussions are ongoing

##### **CSD500: Erectogenic condom**

- Successful product launch in the Middle East
- Regulatory approval of additional brand names and packaging, enabling launch in several EU countries
- Strategic consideration currently being given to commercialisation options for the countries covered by the Church & Dwight agreement, notice of termination of which was received in August 2017

##### **Pain relief products TPR100 (diclofenac) and TIB200 (ibuprofen)**

- First out-licensing agreement signed in January 2017 for TPR100 in the UK
- UK regulatory submission for TPR100 targeted for Q1 2018
- Ongoing out-licensing discussions for TIB200 and TPR100 outside of the UK

#### **Financial**

- Net loss of £1.60 million in the period (H1 2016: net loss £1.89 million), reflecting planned reduction in R&D expenditure in preparation for MED clinical programme commencing in H2 2017
- Cash resources of £10.12 million at 30 June 2017 (30 June 2016: £2.90 million)

**James Barder, Futura's Chief Executive, commented:** "Futura made excellent progress in the first half of 2017 with MED2002, our breakthrough erectile dysfunction gel, which is moving close to its Phase III programme. This exciting programme brings the potential for significant prescription sales and the prospect of an OTC switch in the future. We are currently in commercial discussions with potential licensing partners for MED2002 and we look forward to announcing a licensing agreement in due course. Our novel erectogenic condom, CSD500, has now been launched by our first distributor and we anticipate further launches in the months ahead."

A meeting for analysts will be held at 11.00am this morning, 12 September 2017, at the offices of Buchanan, 107 Cheapside, London EC2V 6DN. There will be a live webcast of the analyst presentation. If you would like to listen to the webcast, please log on to the following web address approximately 5 minutes before 11.00am:

<http://vm.buchanan.uk.com/2017/futuramedical120917/registration.htm>

A recording of the webcast will be made available at [www.futuramedical.com](http://www.futuramedical.com) following the results meeting.

**For further information please contact:**

**Futura Medical plc**

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**Notes to Editors**

**Futura Medical plc**

Futura Medical is a pharmaceutical group that develops innovative products for consumer healthcare. The Company is developing a portfolio of products and its strategy is to license their manufacture and distribution to major pharmaceutical and healthcare groups.

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)

## **Chairman's and Chief Executive's Review**

During the year to date we have continued to advance our pipeline of product opportunities and have made particular progress with MED2002, our topical gel for erectile dysfunction ("ED"), which is progressing to the start of the Phase III clinical programme required ahead of regulatory submission.

CSD500, our novel erectogenic condom, has been launched in the Middle East, with over 500,000 condoms sold to date, and we are working with our partners on launches in other countries. However it was very disappointing that last month Church & Dwight, which had licensing rights to CSD500 in North America and certain European countries, decided to terminate its licensing agreement. We understand from Church & Dwight that this was due to a strategic change by them. Church & Dwight also confirmed that their testing of the product re-confirmed the safety and clinical results that we have previously obtained. The CSD500 product is now "market ready" for distribution we have received verbal confirmation of the approval of additional brand names and pack design with relevant certification expected by the end of September. This will enable launches by our distributors to proceed in a number of other European countries, not covered by the Church & Dwight agreement. We are therefore planning to expand the number of countries where the product is launched within the European Union ("EU"). At the same time we are actively considering commercial options for countries previously licensed to Church & Dwight, including digital marketing of CSD500 within the EU countries.

The commercialisation of our pain relief portfolio continues on track, with the UK regulatory submission for TPR100, our diclofenac gel for topical pain relief, targeted to take place in Q1 2018 by Thornton & Ross, a UK subsidiary of STADA Arzneimittel AG ("STADA").

Regulatory work has been a prominent feature in the year to date reflecting strategies to commercialise our portfolio across the greatest geographical reach. Across Europe, there has been a consolidation of the "Notified Bodies" able to issue regulatory approvals for medical devices, such as CSD500, with the result that it is taking additional time to gain the required approvals. We have therefore worked collaboratively with BSI, the UK based Notified Body, to prioritise our submissions to minimise the impact of delays. During the half year, we recruited a full time regulatory affairs director from the pharmaceutical industry to strengthen our in-house capability and optimise the use of our network of external consultants.

Our balance sheet includes cash resources of £10.12 million as at 30 June 2017 (30 June 2016: £2.90 million). We will continue to use these cash resources prudently through careful consideration of the design and ongoing scrutiny of our clinical trial programmes.

### Portfolio updates - Sexual healthcare

MED2002: Eroxon® Treatment for erectile dysfunction

MED2002, which uses our DermaSys® drug delivery system, is the development name for our topical gel for the treatment of men with ED. We hold patents to the product in a market worth US\$5.6 billion<sup>1</sup> for currently available treatments and have registered the brand name Eroxon®, though potential distributors may choose to use other brand names. MED2002's rapid onset of action means that it has the potential to become the world's fastest-acting treatment for ED.

We announced breakthrough clinical results in September 2016 for MED2002 and these results were shared in face-to-face meetings with the UK and US regulatory authorities in March and April 2017. Both meetings were highly constructive regarding the finalisation of data requirements to achieve approval in the UK, Europe and the US. Both authorities suggested we include a range of doses of MED2002, including the original dose, in the upcoming Phase III studies to achieve the broadest possible indications to cover mild, moderate and severe ED.

Since our last update on MED2002, in July 2017, we have decided to amend the sequencing of this Phase III programme. It is now planned to commence the 40 subject pharmacokinetic (“PK”) study, as soon as possible during Q4 2017 with completion in Q1 2018, this will enable us to check the tolerance to higher doses and define the exact doses to be used in the Phase III trials in 2018. This will avoid the inclusion of unacceptably high doses in the Phase III studies. Meanwhile, planning for the two Phase III studies has continued and detailed protocols have been defined. Final regulatory endorsement shall be sought from European regulatory authorities in October and from the US FDA under the mechanism of a formal IND submission to be made in September. Running the PK and Phase III studies in sequence allows us more time to consult with regulatory authorities and we anticipate that this will mean that the number of active doses can be reduced from four to three in the Phase III study, thereby reducing cost and the time required to complete patient recruitment, with an expected 10% overall reduction in the number of patients required.

The filing will be made in the USA using the 505(2)(b) route in which safety data from another product can be used provided that similarity is demonstrated. In Europe the intent is to follow the decentralised procedure under Article 8(3), subject to regulatory confirmation, which will enable us to reference the long history of safe use of the active ingredient for other indications. This regulatory route will also give us 10 years of data exclusivity, from the date of approval, thereby further strengthening our intellectual property position.

We have had substantial interest in MED2002 from potential licensing partners, seeking both global and regional deals. We continue to work towards our objective of being able to announce a licensing deal by the end of the year, based on existing negotiations.

MED2002, as a topically applied gel with a very rapid speed of onset, has the potential to be a significant product with combined forecast peak sales of more than US\$1 billion in a market currently dominated by Viagra® and Cialis® which are taken orally and do not take effect for at least 30 minutes and typically one hour or more<sup>2</sup>.

MED2002 has substantial potential in the treatment of ED, as the fastest-acting compound with a favourable safety profile, in the prescription market where it will be marketed first. These characteristics also give MED2002 the potential to become one of the largest over-the-counter (“OTC”) products in the global OTC marketplace as it has strong potential to be switched from prescription to OTC status, after a period of marketing on prescription, to extend the commercial potential. As announced earlier this year, the market research firm Ipsos used its validated healthcare forecasting model to forecast peak OTC annual sales for MED2002 in key countries worldwide of more than US\$650 million. Importantly, Ipsos forecasts that some 73% of these potential OTC sales would be incremental to the prescription category. The Ipsos valuation was based on the outcomes from primary market research carried out amongst 400 men, with ED or suspected ED, in the USA. The respondents were shown a concept about MED2002 as part of the market research but they did not use the product as it is currently in clinical development. The key findings of the

market research showed that the respondents believed that the product, once approved, would be highly differentiated from existing products and that its claims would meet their needs. MED2002's rapid onset of action was the key feature that attracted respondents to the product.

MED2002's patent protection runs until August 2028 in the USA and August 2025 in Europe. An additional patent filing announced earlier this year could extend patent protection through to 2038.

*Note <sup>1</sup> IMS Health - MSP 2016 (15 key countries)*

*Note <sup>2</sup> US patient information for Viagra<sup>®</sup> and Cialis<sup>®</sup>*

CSD500: Condom containing the erectogenic Zanafil<sup>®</sup> gel

CSD500 benefits from three clinically proven claims: the maintenance of a firmer erection, maximised penile size and a longer lasting sexual experience for women. CSD500, which is CE Marked, represents real innovation in an industry where there has been limited new product development. Futura's unique intellectual property for CSD500 has been protected throughout the world through the filing and granting of a range of patents.

Consent to use additional brand names and pack design for additional EU countries, with an already CE Mark approved product, continues to take considerable time owing to the changing structure of the EU regulatory bodies, and we have therefore prioritised our submissions in order of commercial relevance as far as possible. We have received verbal confirmation of approval of additional brand names and pack design with relevant certification expected by the end of September. This will enable launches by our distributors to proceed in a number of EU countries.

CSD500 was launched in Saudi Arabia in the first half by our distributor Kabey and further launches in the MENA region are planned as soon as the necessary regulatory approvals on a country by country basis are granted. Kabey is using the brand name Futura Max Manex Super and its promotion is based on direct retail marketing rather than an online campaign. Kabey will shortly receive its third shipment of stock, to date 540,000 condoms have been sold with initial feedback from users of the product being positive.

CSD500 is proceeding to launch in other countries, subject to relevant regulatory approvals, though we were disappointed that Church & Dwight, which had licensing rights to CSD500 in North America and certain European countries, decided to terminate its licensing agreement and return the associated marketing rights, as announced last month. We are actively considering commercial options, including digital marketing of CSD500 within the EU, and will inform shareholders once a decision is reached on how we plan to commercialise CSD500 in those countries previously licensed to Church & Dwight.

Last year we successfully modified the manufacturing process to achieve an extended shelf life for CSD500 to meet the requirements of our distribution partners. Both of our manufacturing partners - TTK in India and our European manufacturer - have the required approvals to ship CSD500 to any country in which the product is approved. During the first half of this year TTK received regulatory approval from the relevant EU Notified Body to manufacture the extended shelf life product. We continue to await approval from the same EU Notified Body of the extended shelf life product for our European based manufacturer, which is now our top priority with that Notified Body.

## **Portfolio updates - Topical pain relief**

The rapid skin permeation rates offered by Futura's transdermal delivery system, DermaSys<sup>®</sup>, have created a major opportunity in topical pain relief. Rapid skin permeation offers potential benefits in pain management including: improved onset of action, duration and degree of pain relief. DermaSys<sup>®</sup> also allows the potential to have a twice daily dosing regimen which provides a compelling commercial proposition for ibuprofen which is currently dosed three to four times per day.

Futura has previously demonstrated statistically significant results from its two non-steroidal anti-inflammatory drug ("NSAID") programmes, TPR100 (2% diclofenac gel) and TIB200 (10% ibuprofen gel), in a clinical study.

Thornton & Ross, part of STADA, holds the UK rights to TPR100, our novel diclofenac gel for pain relief. We expect the regulatory filing for marketing authorisation to be made by Thornton & Ross early next year. Under the terms of its licensing agreement, Thornton & Ross holds rights to manufacture, market and distribute TPR100 in the UK for the lifetime of the product's patents, which run to 2028 in the UK.

We continue in licensing discussions in respect of the commercialisation of TPR100 outside of the UK and are also in discussions in connection with our ibuprofen based product TIB200. As previously stated, we do not intend to conduct any further clinical work without a clear indication of interest and commitment from potential commercial partners.

Our objective is for our pain relief products to be best-in-class. The rationale for this is that the National Institute for Health and Care Excellence (NICE) gives clear guidance to physicians to prescribe topical NSAIDs in the first instance for joint pain associated with osteoarthritis, in preference to oral NSAIDs, owing to concerns over the long term use of oral NSAIDs. This means that the best-in-class topical treatment should be the first choice for doctors in the initial treatment of pain and therefore represents a substantial opportunity in a market with global sales estimated at US\$2.9 billion<sup>3</sup>.

### Outlook

Futura made excellent progress in the first half of 2017 with MED2002, our breakthrough erectile dysfunction gel, which is moving close to its Phase III programme. This exciting programme brings the potential for significant prescription sales and the prospect of an OTC switch in the future. We are currently in commercial discussions with potential licensing partners for MED2002 and we look forward to announcing a licensing agreement in due course. Our novel erectogenic condom, CSD500, has now been launched by our first distributor and we anticipate further launches in the months ahead.

John Clarke

James Barder

Chairman

Chief Executive

*Note <sup>3</sup> IMS Health Estimate, MSP, 2015*

# Group Statement of Comprehensive Income

	Notes	Unaudited 6 months ended 30 June 2017 £	Unaudited 6 months ended 30 June 2016 £	Audited year ended 31 December 2016 £
<b>Revenue</b>	1.5	<b>362,557</b>	66,900	170,362
Research and development costs		<b>(1,764,100)</b>	(1,785,356)	(3,509,680)
Administrative costs		<b>(605,742)</b>	(548,803)	(1,214,755)
<b>Operating loss</b>		<b>(2,007,285)</b>	(2,267,259)	(4,554,073)
Finance income		<b>9,419</b>	7,037	14,714
<b>Loss before tax</b>		<b>(1,997,866)</b>	(2,260,222)	(4,539,359)
Taxation		<b>401,422</b>	369,058	842,246
<b>Total comprehensive loss for the period attributable to owners of the parent company</b>		<b>(1,596,444)</b>	(1,891,164)	(3,697,113)
Loss per share (pence)	3	<b>(1.32p)</b>	(1.91p)	(3.65p)

All amounts relate to continuing activities.

# Group Statement of Changes in Equity

	Share Capital £	Share Premium £	Merger Reserve £	Retained Losses £	Total Equity £
<b>At 1 January 2016 - audited</b>	<b>198,185</b>	<b>33,053,345</b>	<b>1,152,165</b>	<b>(29,617,464)</b>	<b>4,786,231</b>
Total comprehensive loss for the period	-	-	-	(1,891,164)	(1,891,164)
Share-based payment	-	-	-	60,200	60,200
<b>At 30 June 2016 - unaudited</b>	<b>198,185</b>	<b>33,053,345</b>	<b>1,152,165</b>	<b>(31,448,428)</b>	<b>2,955,267</b>
Total comprehensive loss for the period	-	-	-	(1,805,949)	(1,805,949)
Share-based payment	-	-	-	(5,795)	(5,795)
Shares issued during the period	42,105	11,957,895	-	-	12,000,000
Cost of share issue	-	(559,495)	-	-	(559,495)
<b>At 31 December 2016 - audited</b>	<b>240,290</b>	<b>44,451,745</b>	<b>1,152,165</b>	<b>(33,260,172)</b>	<b>12,584,028</b>
Total comprehensive loss for the period	-	-	-	(1,596,444)	(1,596,444)
Share-based payment	-	-	-	90,469	90,469
Shares issued during the period	1,027	198,267	-	-	199,294
<b>At 30 June 2017 - unaudited</b>	<b>241,317</b>	<b>44,650,012</b>	<b>1,152,165</b>	<b>(34,766,147)</b>	<b>11,277,347</b>

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

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 using merger accounting under UK GAAP.

Retained losses represent cumulative net losses recognised in the Group Statement of Comprehensive Income. The total comprehensive loss for the year represents the total recognised income and expense for the year.



# Group Statement of Financial Position

	Notes	Unaudited 30 June 2017 £	Unaudited 30 June 2016 £	Audited 31 December 2016 £
<b>Assets</b>				
<b>Non-current assets</b>				
Plant and equipment		48,118	17,283	21,351
<b>Total non-current assets</b>		<b>48,118</b>	<b>17,283</b>	<b>21,351</b>
<b>Current assets</b>				
Inventories		83,632	197,733	83,641
Trade and other receivables	4	151,909	179,114	138,989
Current tax asset		1,243,668	369,058	842,246
Cash and cash equivalents	5	10,122,625	2,900,248	12,352,978
<b>Total current assets</b>		<b>11,601,834</b>	<b>3,646,153</b>	<b>13,417,854</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Trade and other payables		(372,605)	(708,169)	(855,177)
<b>Total liabilities</b>		<b>(372,605)</b>	<b>(708,169)</b>	<b>(855,177)</b>
<b>Total net assets</b>		<b>11,277,347</b>	<b>2,955,267</b>	<b>12,584,028</b>
<b>Capital and reserves attributable to owners of the parent company</b>				
Share capital		241,317	198,185	240,290
Share premium		44,650,012	33,053,345	44,451,745
Merger reserve		1,152,165	1,152,165	1,152,165
Retained losses		(34,766,147)	(31,448,428)	(33,260,172)
<b>Total equity</b>		<b>11,277,347</b>	<b>2,955,267</b>	<b>12,584,028</b>

# Group Statement of Cash Flows

	Unaudited 6 months ended 30 June 2017 £	Unaudited 6 months ended 30 June 2016 £	Audited year ended 31 December 2016 £
<b>Cash flows from operating activities</b>			
Loss before tax	(1,997,866)	(2,260,222)	(4,539,359)
Adjustments for:			
Depreciation	(6,005)	3,332	6,247
Finance income	(9,419)	(7,037)	(14,714)
Share-based payment charge	90,469	60,200	54,405
<b>Cash flows from operating activities before changes in working capital</b>	<b>(1,922,821)</b>	<b>(2,203,727)</b>	<b>(4,493,421)</b>
Decrease / (increase) in inventories	9	(33,966)	80,126
(Increase) / decrease in trade and other receivables	(12,920)	(21,815)	16,981
(Decrease) / increase in trade and other payables	(482,572)	(45,724)	101,284
<b>Cash used in operations</b>	<b>(2,418,304)</b>	<b>(2,305,232)</b>	<b>(4,295,030)</b>
Income tax received	-	997,036	997,036
<b>Net cash used in operating activities</b>	<b>(2,418,304)</b>	<b>(1,308,196)</b>	<b>(3,297,994)</b>
<b>Cash flows from investing activities</b>			
Purchase of plant and equipment	(20,762)	(500)	(7,483)
Interest received	9,419	20,650	29,656
<b>Cash (absorbed) / generated by investing activities</b>	<b>(11,343)</b>	<b>20,150</b>	<b>22,173</b>
<b>Cash flows from financing activities</b>			
Issue of ordinary shares	199,294	-	12,000,000
Expenses paid in connection with share issues	-	-	(559,495)
<b>Cash generated by financing activities</b>	<b>199,294</b>	<b>-</b>	<b>11,440,505</b>
<b>(Decrease) / increase in cash and cash equivalents</b>	<b>(2,230,353)</b>	<b>(1,288,046)</b>	<b>8,164,684</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>12,352,978</b>	<b>4,188,294</b>	<b>4,188,294</b>
<b>Cash and cash equivalents at end of period</b>	<b>10,122,625</b>	<b>2,900,248</b>	<b>12,352,978</b>

## Notes to the Group Interim Financial Information

### 1. Accounting policies

#### 1.1 Basis of preparation

The unaudited Interim Report was approved by the Board of Directors on 11 September 2017.

The interim financial information for the six months ended 30 June 2017 and for the six months ended 30 June 2016 does not constitute statutory accounts within the meaning of section 434(3) of the Companies Act 2006 and is unaudited.

The Group financial information for the year ended 31 December 2016 which 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 2016, does not constitute the full statutory accounts for that period. The Annual Report for 2016 has been filed with the Registrar of Companies. The Independent Auditor’s Report on those financial statements was unqualified, did not draw attention to any matters by way of emphasis and did not contain a statement under sections 498(2) or 498(3) of the Companies Act 2006.

#### 1.2 Going concern

The Group had an operating loss of £2.01 million for the period (H1 2016: £2.27million; 2016 financial year: £4.55 million), but had a positive net asset value of £11.28 million at 30 June 2017 (30 June 2016: £2.96 million; 31 December 2016: £12.58 million).

The Group had cash balances of £10.12 million at 30 June 2017, with a net cash outflow of £2.23 million in the period (30 June 2016: £2.90 million and a net cash outflow of £1.29 million; 31 December 2016: £12.35 million and a net cash inflow of £8.16 million). The Directors consider this to represent sufficient funds for the foreseeable future, taking into account the Group’s current development plans.

In assessing the Group’s going concern ability the Directors have considered all relevant available information about the future trading activities of the Group, including profit forecasts, cash forecasts and funding. Based on this assessment, the Interim Report has been prepared on a going concern basis and the Directors have no reason to believe that the Group will not operate as a going concern for the foreseeable future.

#### 1.3 Accounting developments

The following new standards, amendments and interpretations, which are not yet effective and have not been adopted early in these financial statements do not currently have a material impact, but the future impact will be considered on an ongoing basis:

- IFRS 15 Revenue from Contracts with Customers (effective 1 January 2018)
- IFRS 9 Financial Instruments (effective 1 January 2018)
- IFRS 16 Leases (effective 1 January 2019)

#### **1.4 Basis of consolidation**

Where the Company has the power, either directly or indirectly, to govern the financial and operating policies of another entity or business, so as to obtain benefits from its activities, it is classified as a subsidiary. The Group financial information present the results of the Company and its subsidiaries Futura Medical Developments Limited and Futura Consumer Healthcare Limited as if they formed a single entity ("the Group"). Intra-group transactions and balances are eliminated in preparing the Group financial information.

#### **1.5 Revenue**

Revenue comprises the fair value received or receivable for milestone income and royalties, net of value added tax.

The accounting policies for the principal revenue streams of the Group are as follows:

- (i) Non-refundable milestone income is recognised as revenue in the accounting period in which the milestones are achieved. If any milestone income is creditable against royalty payments then it is deferred and released to the Consolidated Statement of Comprehensive Income over the accounting periods in which the royalties would otherwise be receivable.
- (ii) Royalty income relating to the sale by a licensee of licensed product is recognised on an accruals basis in accordance with the substance of the relevant agreement and based on the receipt from the licensee of the relevant information to enable calculation of the royalty due.

#### **1.6 Leased assets**

Leases which contain terms whereby the Group does not assume substantially all the risks and rewards incidental to ownership of the leased item are classified as operating leases. Operating lease rentals are charged to the Group Statement of Comprehensive Income on a straight-line basis over the lease term. The Group does not hold any assets under finance leases.

#### **1.7 Intangible assets**

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

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

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

Capitalised development costs are amortised over the periods in which the Group expects to benefit from selling the products developed but not exceeding five years. The amortisation expense is included in R&D

costs recognised in the Group Statement of Comprehensive Income. The useful life and the value of the capitalised development cost are assessed for impairment at least annually. The value is written down immediately if impairment has occurred and the unimpaired cost amortised over the reduced useful life. The Directors consider that the criteria to capitalise development expenditure are not met for a product prior to that product being commercially launched in at least one country.

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

#### **Patents and trademarks**

Costs incurred in establishing patents and trademarks are either expensed or capitalised in accordance with the corresponding treatment of the development expenditure for the product to which they relate.

### **1.8 Plant and equipment**

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

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

### **1.9 Impairment of non-financial assets**

Assets that are subject to depreciation are reviewed for impairment on a half-yearly basis and when events or circumstances suggest that the carrying amount may not be recoverable. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash generating units). An impairment loss is recognised immediately in the Group Statement of Comprehensive Income for the amount by which the asset's carrying amount exceeds its recoverable amount.

Recoverable amount is the higher of fair value, less disposal costs, and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset in prior periods. A reversal of an impairment loss is recognised immediately in the Group Statement of Comprehensive Income.

### **1.10 Inventories**

Inventories are materials and supplies to be consumed in the course of R&D and are initially recognised at cost, and subsequently at the lower of cost and net realisable value. Cost includes materials, related

contract manufacturing costs and other direct costs. Cost is calculated using the first-in, first-out method. Net realisable value is based on estimated selling price, less further costs expected to be incurred to completion and disposal.

A provision is recognised immediately in the Group Statement of Comprehensive Income in respect of obsolete, slow-moving or defective items, where appropriate.

## **1.11 Financial instruments**

### ***Financial assets***

The Group classifies its financial assets in the category of loans and receivables, comprising 'trade and other receivables' and 'cash and cash equivalents'. They are recognised initially at fair value and subsequently at amortised cost using the effective interest rate method.

Trade and other receivables are recognised initially at fair value and are subsequently measured at amortised cost using the effective interest rate method, less an estimate made for impairment based on a review of all past due amounts at the year end. A provision for impairment of trade and other receivables is established when there is objective evidence that the Group will not be able to collect all amounts due. If an impairment loss is required the carrying amount of the trade or other receivable is reduced through the use of an allowance account and the amount of the loss recognised immediately in the Consolidated Statement of Comprehensive Income in administrative costs.

Cash and cash equivalents are financial assets and comprise cash in hand and sterling short-term money market funds which are held by the Group so as to be available to meet short-term cash commitments.

The Group assesses at each Consolidated Statement of Financial Position date whether there is objective evidence that a financial asset is impaired.

### ***Financial liabilities***

The Group's financial liabilities comprise 'trade and other payables' recognised initially at fair value and subsequently at amortised cost using the effective interest rate method.

## **1.12 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.

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.

### **1.13 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.

### **1.14 Employee benefits**

#### *(i) 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.

#### *(ii) 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.

#### *(iii) Share-based payment transactions*

The Group operates an equity-settled share-based compensation plan. For 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 vesting, the change in the fair value of the share options, measured immediately before and after the modification, is 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 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.

#### *(iv) 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 can exercise discretion in settling any award in equity or in cash.

### **1.15 Finance income**

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

### **1.16 Critical accounting estimates, assumptions and judgements**

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.

#### **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.

#### **Judgements**

##### *Deferred tax recognition*

The determination of probable future profits, against which the Group's deferred tax profits can be offset, requires judgement.



## 2. Segment reporting

The Group is organised and operates as one segment. The Group's revenue analysed by geographical location of the Group's customers is:

	<b>Unaudited 6 months ended 30 June 2017 £</b>	Unaudited 6 months ended 30 June 2016 £	Audited 12 months ended 31 December 2016 £
Middle East / ROW	<b>12,557</b>	21,208	118,192
United States of America	-	35,473	35,473
Europe	<b>350,000</b>	10,219	16,697
	<b>362,557</b>	66,900	170,362

## 3. Loss per share (pence)

The calculation of the loss per share is based on a loss of £1,596,444 (six months ended 30 June 2016: loss of £1,891,164; year ended 31 December 2016: loss of £3,697,113) and on a weighted average number of shares in issue of 120,603,347 (six months ended 30 June 2016: 99,092,318; year ended 31 December 2016: 101,350,836). 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'.

## 4. Trade and other receivables

	<b>Unaudited 30 June 2017 £</b>	Unaudited 30 June 2016 £	Audited 31 December 2016 £
Amounts receivable within one year:			
Trade receivables	<b>6,428</b>	33,711	20,364
Other receivables	<b>10,870</b>	46,402	14,622
Prepayments and accrued income	<b>134,611</b>	99,001	104,003
	<b>151,909</b>	179,114	138,989

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 Group Statement of Financial Position date is the fair value of each class of receivable.

## 5. Cash and cash equivalents

	<b>Unaudited 30 June 2017 £</b>	Unaudited 30 June 2016 £	Audited 31 December 2016 £
Cash at bank and in hand	<b>258,588</b>	70,021	147,200
Sterling fixed rate short-term deposits	<b>9,864,037</b>	2,830,227	12,205,778
	<b>10,122,625</b>	2,900,248	12,352,978

## 6. 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.

## **Company number**

4206001

## **Directors**

John Clarke	Non-Executive Chairman
James Barder	Chief Executive
Derek Martin	Finance Director
Jonathan Freeman	Non-Executive Director
Ken James	Non-Executive Director

## **Audit committee**

Jonathan Freeman  
Ken James

## **Remuneration committee**

Jonathan Freeman  
John Clarke

## **Nominations committee**

John Clarke  
Jonathan Freeman

## **Secretary and registered office**

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