Futura Medical plc
13 SEPTEMBER 2022

INTERIM RESULTS FOR THE SIX MONTHS END 30 JUNE 2022

Futura Medical plc (AIM: FUM), a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® drug delivery technology and currently focused on sexual health and pain, is pleased to announce its unaudited interim results for the six months ended 30 June 2022.

Operational Highlights

MED3000 – Regulatory

- **Europe:** MED3000 will be the first pan-European topical treatment for erectile dysfunction ("ED") available without the need of a doctor's prescription ("OTC").
    - In April 2022, Futura received approval for a UKCA mark for MED3000, supplementing the CE Mark approval received in April 2021.
- **US:** In August 2022, Futura received highly positive results from the confirmatory Phase 3 clinical study, ("FM71") for MED3000 for the treatment of ED meeting all primary and secondary endpoints.
    - Results demonstrated that MED3000 presents an effective clinically proven treatment for ED with a rapid speed of onset and a favourable benefit versus risk profile ideally suited for OTC classification.
    - Futura expects to file a regulatory dossier with the US Food and Drug Administration ("FDA") by the end of September 2022, targeting marketing authorisation for MED3000 in Q1 2023 as the first major ED treatment available OTC throughout the USA.

MED3000 – Commercialisation & Manufacturing

- Futura has signed multiple commercial agreements to date across key markets, as it continues to build a strong network of licensing and distribution partners with strength in brand building, pharmaceutical credibility and marketing expertise for long-term distribution of MED3000 across the globe.
    - In March 2022, Futura announced that it had entered into a licensing agreement with Menarini Korea, a wholly owned subsidiary of Menarini Group, for the exclusive rights to commercialise MED3000 in South Korea.
    - In May 2022, Futura announced an exclusive licensing agreement with Cooper Consumer Health for the rights to commercialise MED3000 throughout the European Economic Area, the United Kingdom and Switzerland. Plans are at an advanced stage for initial launches in first half of 2023.

    - Following successful completion of FM71, Futura's specialist corporate advisors have now formally commenced the search for a US partner.
- Through its commercial partners, Futura aims to launch MED3000 and build a respected, high quality, and trusted global brand. Futura's contract manufacturing supply chain is now ready for commercial production, with capacity for initial launch supplies of Eroxon™ and beyond. Eroxon™ has an approved shelf-life of 42 months which will provide at least 3 years shelf-life at point of sale. First manufacturing orders have been received from our European partner.
- Regulatory approvals for a number of non-EU markets through Futura's commercial partners are progressing well other than in China where the regulatory approval for MED3000 remains a number of years away.
- Futura has recently completed additional national patent applications in line with normal PCT filing procedure in all key ED markets in order to protect the commercial interests of MED3000. If national patents applications are successful, this will provide patent protection until 2040.

Board updates

- Futura strengthened the Board with the appointment of Andrew Unitt, who was previously Finance director of Boots Healthcare International, as a non-executive director as of 1 January 2022.

Financial Highlights

- £2.50 million net losses in the period (30 June 2021: net total loss £1.59 million).
- Cash resources of £6.68 million at 30 June 2022 (excluding tax credit due of £0.91 million).
- Current cash runway extends well beyond expected initial MED3000 launches in the coming months and expected US regulatory approval in Q1 2023.

James Barder, Chief Executive Officer, Futura Medical said: "I am delighted with the significant progress we have made during the first half of the year as we continue to deliver on the Company's strategic objectives. The whole team at Futura looks forward with growing excitement to the launch of Eroxon™ in the coming months as we, in close alignment with our commercial partners, work hard to build Eroxon™ into a long term, profitable and trusted brand."

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 volatile solvent component formulations tailored for each product to suit the specific therapeutic indication and desired speed of onset and duration of action. Such targeted delivery offers an optimised profile in terms of dose, onset time and duration of effect as well as an improved safety profile reducing the risk of side effects. Each product is formulated to maximise its benefits for patients and consumers. Each new unique formulation offers the opportunity for additional patent applications and potential patent protection.

MED3000 – breakthrough, fast acting topical gel formulation for the treatment of Erectile Dysfunction ("ED")

MED3000 is CE marked in Europe and CA marked in the UK, as a clinically proven topical treatment for adult men with ED that helps men get an erection within 10 minutes.

Studies have shown MED3000 to be an effective treatment for ED with an excellent safety profile. MED3000 has a unique evaporative mode of action which the Company believes stimulates nerve endings in the glans penis to cause an erection.

MED3000 helps men get an erection within 10 minutes, faster than on-demand oral tablet phosphodiesterase-5 inhibitors ("PDE5is" – oral treatments for the treatment of ED such as Viagra® Levitra ® and Cialis ® and their generic equivalents), with significant benefits for spontaneous rather than pre-planned sexual intercourse.

The prevalence of ED disrupts the lives of at least 1 in 5 men globally with around 23 million men suffering ED in the US and 20 million men in the UK, France, Italy, Spain and Germany[1]. There has been little innovation in ED treatments for nearly two decades and many patients continue to suffer dissatisfaction with existing treatments. The US market, in particular, continues to evolve following the expiry of the PDE5i's patent protection with the advent of subscription services such as For Hims and Go Roman which offer a branded concierge service for ED prescription medicines online. This increased affordability of generic PDE5is is driving volumes especially in the US which have increased by 85% between 2018 and 2020[2].

Recent US market research conducted by IPSOS and commissioned by Futura has confirmed that even with increasing volumes the requirement of a doctor's prescription remains both an economic and emotional barrier to use: US patients spend between US$600 and US$3,500 per annum on ED treatments, when taking into account both prescription costs and doctors' visits not covered by insurance[3]. This reconfirms the significant opportunity that MED3000 represents with OTC availability at a likely retail price in the region of US$5 per dose in the USA.

MED3000 - approved as the first pan-European topical treatment for ED available with OTC status

Futura's breakthrough, fast-acting topical gel formulation MED3000, is the first clinically proven, pan-European topical treatment for adult men with ED available without a doctor's prescription.

In April 2021, the Company received its MDR EU Quality Management Certificate for the placing on the market of a Class 2B medical device known as MED3000 ("CE mark approval").

The CE mark approval of MED3000 from the EU Notified Body paves the way for approval in many countries around the world, including in Latin America, the Middle East, Africa and the Far East regions, with many countries considering "fast-track" review based on recognition of the EU CE mark.

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

US - the largest potential OTC ED market globally

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

In 2021 Futura received official minutes from the FDA agreeing the design for a confirmatory, Phase 3 clinical trial, (“FM71”), designed to provide supplementary efficacy data to the previously reported Phase 3 clinical study (“FM57”) study.

FM71 – Highly positive results with all primary and secondary endpoints achieved

In August 2022, Futura announced positive results from FM71, broadly comparable with data generated in both FM57 and a recent “real world”, home use study.

FM71 was a multi-centre, randomised, open-label, home use, parallel group, clinical investigation of MED3000 compared to oral tadalafil (5mg) tablets. The trial design and clinical endpoints were agreed with the FDA and the trial used gold standard, internationally accepted clinical trial endpoints in ED.

FM71 investigated the efficacy and safety of MED3000 gel in 96 male patients (recruited from the United States (African Americans), Poland, Georgia and Bulgaria) clinically diagnosed with a mix of mild, moderate and severe ED against baseline (pre-treatment).

FM71 results demonstrated that MED3000 presents an effective clinically proven treatment for ED with a 10-minute onset of action and a favourable benefit versus risk profile ideally suited for OTC classification.

Futura is on track to file a full regulatory dossier with the FDA by the end of September 2022, targeting marketing authorisation by the FDA of MED3000 in Q1 2023 as the first major ED treatment available OTC throughout the USA.

MED3000 – Commercialisation & Manufacturing

Futura is establishing a network of licensing and distribution partners with strength in brand building, pharmaceutical credibility and regional infrastructure and marketing expertise for long-term distribution of MED3000 (Eroxon™) across the globe.

With multiple commercial agreements in key markets, Futura now has a strong and expanding distribution platform in place for regions outside the key US market.

Menarini Korea Limited ("Menarini Korea") – South Korea

In March 2022, Futura announced that it had entered into a licensing agreement with Menarini Korea, a wholly owned subsidiary of Menarini Group, for the exclusive rights to commercialise MED3000 in South Korea.

Under the terms of the agreement, Menarini will be responsible for all costs related to the regulatory approval and marketing of the product in the region, including a clinical bridging study if necessary. Futura will provide reasonable technical support for product development and commercialisation and will receive an upfront payment and provide manufactured product from Futura's 3rd party contract manufacturers.

Cooper Consumer Health ("Cooper") – European Economic Area, United Kingdom and Switzerland

In May 2022, Futura announced an exclusive licensing agreement with Cooper, a leading European independent self-care organisation, for the rights to commercialise MED3000 throughout the European Economic Area ("EEA"), the United Kingdom and Switzerland.

Under the terms of the agreement, Futura will receive an initial upfront payment, as well as undisclosed cumulative sales milestone payments and will manufacture and supply the product (through its 3rd party contract manufacturers) for the EEA, the United Kingdom and Switzerland to Cooper. The agreement is for an initial term of five years complying with EU competition law. Futura will remain Legal Manufacturer[4] and be responsible for the supply of MED3000 through its 3rd party contract manufacturers.

US commercialisation strategy

Following positive FM71 results announced in August 2022, Futura is on track to file a dossier with the FDA by the end of September 2022, targeting marketing authorisation by the FDA of MED3000 in Q1 2023 as the first major ED treatment available OTC throughout the USA.

In line with the Board's US commercialisation strategy following the successful completion of FM71 and expected imminent FDA dossier submission, Futura has recently commenced the search for a US commercial partner through its specialist corporate advisors. Futura has already received a number of inquiries regarding commercialisation opportunities for MED3000 for the key US market and the Board along with its advisors are focussed on securing the best options in order to maximise long-term value and sustainable revenues whilst minimising risk for Futura's shareholders.

China and Southeast Asia

The current political environment and restrictive "Zero-Covid" policy in China has resulted in Co-High Investment Management Limited not being able to deliver to-date on the key development and regulatory milestones as set out in the agreement entered into between the companies in March 2021. Futura is exploring options to remedy this situation in line with the contractual terms of the agreement as Southeast Asia including China remains a significant commercial opportunity, although further Phase 3 trials, taking several years, will be required, as previously disclosed.

Manufacturing

The Company engaged a US FDA, EMA and UK approved contract manufacturer in 2021. Manufacturing scale up has now been completed and confirms we have sufficient production capacity to meet projected initial demand and beyond. This manufacturer is now ready for commercial production and first manufacturing orders have been received from Futura's European partner. Options for the addition of further manufacturing sites to increase supply chain robustness continue to progress. MED3000 supply is ISO 13485 accredited with a competitive cost of goods and now has an approved 42-month shelf-life giving significant distribution flexibility mindful of transport times between the country of manufacture and final country of sale.

Intellectual Property: Patents, Trademarks and exclusively supplied, Critical Ingredients

Futura's corporate strategy is to develop layers of protection around its products and in particular MED3000, and the Company continues to work with specialist patent and trademark advisors to further refine and optimise this strategy:

1. In line with normal PCT filing procedures MED3000 patents are now filed in all major ED markets considered necessary to protect the commercial interests of MED3000. A request to the European Patent Office was made in August 2021 for examination of the MED3000 patent application and in Q2 2022 it confirmed the novel and inventive nature of the application, which is required before a patent can be granted, although further review continues.
2. A key excipient in the MED3000 formulation is made by only one known manufacturer who has entered into an exclusivity agreement for the supply of that ingredient (within the sexual health field) for MED3000 manufacturing, providing further competitive protection around MED3000.
3. A high-quality dossier that will shortly be submitted to the FDA will contain substantial safety and effectiveness data. This will be enshrined in Special Controls[5] which would have to be replicated in full by any potential competitors hoping to follow the 510K medical device route using MED3000 as the predicate device to gain FDA marketing authorisation. These controls will present a formidable barrier to competitor entry to the US market.
4. Futura aims to work with commercial partners such that MED3000 is launched, wherever possible, under the Eroxon™ trademark to help establish global awareness, consumer trust and build worldwide brand integrity. In consumer health and over-the-counter markets an established brand name is paramount in providing product price and sales volume stability for many years.

Research and Development

Futura is committed to delivering long-term and sustainable value to the Company allowing a long-lasting growth franchise to be built around MED3000 and other DermaSys® formulated products.

Whereas Futura's priority remains the approval and subsequent successful launch of MED3000 (Eroxon™) in major markets throughout the world, Futura aims to build a significant MED3000 franchise across sexual health by leveraging and expanding its unique knowledge and expertise in underserved and new categories in sexual health, building upon market research already undertaken to identify product extensions and potentially new market segments for an OTC product treating ED. Futura intends, in due course, to commission further in-market research, especially for the US, to identify commercially attractive product line extension opportunities.

Board Changes

Futura continues to bring new skills and experience to its already highly skilled Board.

In January 2022, Andrew Unitt joined the Company as Non-Executive Director. Andrew brings strong financial experience having spent eleven years at Boots plc, where he was Finance Director for four years of Boots Healthcare International, its over-the-counter medicines business. Andrew's OTC market expertise and exceptional skills in strategic development and business management will further enhance Futura's ambition and focus on building a global brand and distribution network to accelerate Company growth.

Andrew chairs the Audit Committee as Jonathan Freeman's successor, following Jonathan stepping down at the end of 2021.

1. EMA, Withdrawal assessment report for Viagra, 2008
2. Manufacturers' Selling Prices, IQVIA 2020 market data
3. Ipsos research commissioned by Futura
4. Legal Manufacture means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device
5. www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents

Financial Review

Research and development costs

Research and development costs for the six months ended 30 June 2022 were £1.91 million, compared to £1.19 million for the six months ended 30 June 2021 with the increase being predominantly due to increased activity related to the FM71 study cost.

Administrative costs

Administrative costs were £0.94 million for the six months ended 30 June 2022 compared to £0.71 million for the six months ended 30 June 2021. The slight increase mainly relates to legal and professional costs associated with concluding MED3000 commercial agreements and supply chain set-up costs.

Going concern

At the period end the Group held £6.68 million of cash with a further £0.91 of R&D tax credits relating to 2021 which is expected to be received in the second half of 2022. The Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Cash runway

The Company continues to have sufficient cash resources beyond initial MED3000 launches and expected US regulatory approval. The current runway does not include any additional revenues from commercial upfront milestones, royalties or other income generated from MED3000 sales.

Outlook

Futura is well advanced in its strategic objective of creating a global network of licensing and distribution partners with strength in brand building, pharmaceutical credibility, infrastructure and marketing expertise for long-term profitable distribution of MED3000 across the world.

We are looking forward to launching MED3000 as a priority under the Eroxon™ brand with multiple commercial agreements in place in key markets and where regulatory approval allows. We are also firmly focussed on gaining marketing authorisation in the key market of the USA and finalising commercial arrangements to enable the marketing of MED3000 as a clinically proven topical treatment for ED with a rapid speed of onset. We look forward to updating shareholders further on regulatory and commercial progress on MED3000.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the six months ended 30 June 2022

	Notes	**Unaudited 6 months ended 30 June 2022**	Unaudited 6 months ended 30 June 2021	Audited year ended 31 December 2021
		£	£	£
Revenue		**-**	-	-
Research and development costs		**(1,909,854)**	(1,192,591)	(3,774,269)
Administrative costs		**(939,921)**	(709,301)	(2,092,042)
Operating loss		**(2,849,775)**	(1,901,892)	(5,866,311)
Finance income		**-**	-	-
Loss before tax		**(2,849,775)**	(1,901,892)	(5,866,311)
Taxation	10	**350,000**	315,000	908,600
Total comprehensive loss for the period attributable to owners of the parent company		**(2,499,775)**	(1,586,892)	(4,957,711)
Loss per share (pence)	5	**(0.87p)**	(0.62p)	(1.83p)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2022

	Notes	**Unaudited 30 June 2022 £**	Unaudited 30 June 2021 £	Audited 31 December 2021 £
Assets				
Non-current assets				
Plant and equipment		**731,911**	32,795	442,657
Total non-current assets		**731,911**	32,795	442,657
Current assets				
Trade and other receivables	6	**99,611**	83,750	79,256
Current tax asset		**1,258,312**	833,805	908,312
Cash and cash equivalents	7	**6,676,249**	12,762,201	10,372,571
Total current assets		**8,034,172**	13,679,756	11,360,139
Liabilities				
Current liabilities				
Trade and other payables	8	**(1,388,830)**	(735,303)	(2,078,184)
Total liabilities		**(1,388,830)**	(735,303)	(2,078,184)
Total net assets		**7,377,253**	12,977,248	9,724,612
Capital and reserves attributable to owners of the parent company				
Share capital	11	**574,593**	574,142	574,302
Share premium		**66,399,546**	66,353,363	66,378,003
Merger reserve		**1,152,165**	1,152,165	1,152,165
Warrant Reserve		**165,868**	165,868	165,868
Retained losses		**(60,914,919)**	(55,268,290)	(58,545,726)
Total equity		**7,377,253**	12,977,248	9,724,612

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the six months ended 30 June 2022

	Notes	Share Capital £	Share Premium £	Merger Reserve £	Other Reserve £	Retained Losses £	Total Equity £
At 1 January 2021 - audited		**491,254**	**52,814,090**	**1,152,165**	**165,868**	**(53,769,837)**	**853,540**
Total comprehensive loss for the period		-	-	-	-	(1,586,892)	(1,586,892)
Share-based payment		-	-	-	-	88,439	88,439
Shares issued during the period		67,888	12,054,273				12,122,161
Convertible loan notes and warrants Issues		-	-	-	118,864	196,909	315,773
Convertible loan notes and warrants conversion and exercise		15,000	1,485,000	-	(118,864)	(196,909)	1,184,227
Transactions with Owners		82,888	13,539,273	-	-	88,439	13,710,600
At 30 June 21 - unaudited		**574,142**	**66,353,363**	**1,152,165**	**165,868**	**(55,268,290)**	**12,977,248**
Total comprehensive loss for the period		-	-	-	-	(3,370,819)	(3,370,819)
Share-based payment		-	-	-	-	93,383	93,383
Shares issued during the period		160	24,640	-	-	-	24,800
Convertible loan notes and warrants issue		-	-	-	-	-	-
Convertible loan notes and warrants conversion and exercise		-	-	-	-	-	-
Transactions with Owners		160	24,640	-	-	93,383	118,183
At 31 December 2021 - audited		**574,302**	**66,378,003**	**1,152,165**	**165,868**	**(58,545,726)**	**9,724,612**
Total comprehensive loss for the period		-	-	-	-	(2,499,775)	(2,499,775)
Share-based payment		-	-	-	-	130,582	130,582
Shares issued during the period		291	21,543	-	-	-	21,834
Convertible loan notes and warrants issue		-	-	-	-	-	-
Convertible loan notes and warrants conversion and exercise		-	-	-	-	-	-
Transactions with Owners		291	21,543	-	-	130,582	152,416
At 30 June 2022 - unaudited		**574,593**	**66,399,546**	**1,152,165**	**165,868**	**(60,914,919)**	**7,377,253**

CONSOLIDATED STATEMENT OF CASH FLOWS

For the six months ended 30 June 2021

	Unaudited 6 months ended 30 June 2022 £	Unaudited 6 months ended 30 June 2021 £	Audited year ended 31 December 2021 £
Cash flows from operating activities			
Loss before tax	**(2,849,775)**	(1,901,892)	(5,866,311)
Adjustments for:			
Depreciation	**12,369**	11,455	19,808
Loss on disposal of fixed assets	**-**	-	125
Share-based payment charge	**130,582**	88,439	181,822
Cash flows used in operating activities before changes in working capital	**(2,706,824)**	(1,801,998)	(5,664,556)
(Increase) / decrease in trade and other receivables	**(20,355)**	(43,960)	(39,466)
Decrease in trade and other payables	**(689,354)**	(31,222)	1,311,659
Cash used in operations	**(3,416,533)**	(1,877,180)	(4,392,363)
Income tax received	**-**	-	519,093
Net cash used in operating activities	**(3,416,533)**	(1,877,180)	(3,873,270)
Cash flows from investing activities			
Purchase of plant and equipment	**(301,623)**	(1,381)	(419,722)
Interest received	**-**	-	-
Cash used in investing activities	**(301,623)**	(1,381)	(419,722)
Cash flows from financing activities			
Issue of ordinary shares	**21,834**	14,294,481	14,319,281
Expenses paid in connection with share issues	**-**	(672,320)	(672,319)
Cash generated by financing activities	**21,834**	13,622,161	13,646,962
Increase/(decrease) in cash and cash equivalents	**(3,696,322)**	11,743,600	9,353,970
Cash and cash equivalents at beginning of period	**10,372,571**	1,018,601	1,018,601
Cash and cash equivalents at end of period	**6,676,249**	12,762,201	10,372,571

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2022

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, 2022 were authorised for issue in accordance with a resolution of the Directors on 12th September, 2022. 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 2021, as described in those financial statements except for the new accounting policies described below.

These condensed interim consolidated financial statements for the six months ended 30 June 2022 and for the six months ended 30 June 2021 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 2021 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 2021 and does not constitute the full statutory accounts for that period. The Annual Report for 2021 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.

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 2022 of £2.50 million (six months ended 30 June 2021: £1.59 million, year ended 31 December 2021: £4.96 million). The Group holds cash balances of £6.68 million at 30 June 2021 (30 June 2021: £12.76 million, 31 December 2021: £10.37 million).

3. Critical accounting judgements, assumptions and estimates
Going concern (continued)

Directors have considered the applicability of the going concern basis in the preparation of the financial statements. This includes the review of internal budget, financial results and cashflow forecasts for the 12 months' period following the date of signing the financial statements. These forecasts show that the Group has sufficient funds to allow the business to continue in operations for at least 12 months from the date of approval of these financial statements.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. The financial statements do not include any adjustments that would result from the basis of preparation being inappropriate.

3.2 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 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 £130,582 for the six months ending June 2022 (six months ended 30 June 2021: £88,439, year ended 31 December 2021: £181,822), the volatility method used is not expected to have a material impact on these financial statements.

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 tax assets have been recognised.

R&D Tax Credits

The current tax receivable represents an estimate of the anticipated R&D tax credit in respect of claims not yet submitted for the 2021 financial year. 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.

4. Segment reporting

The Group is organised and operates as one segment.

5. Loss per share (pence)

The calculation of the loss per share is based on a loss of £2,499,775 (six months ended 30 June 2021: loss of £1,586,892; year ended 31 December 2021: loss of £4,957,711) and on a weighted average number of shares in issue of 287,286,073 (six months ended 30 June 2021: 254,590,594; year ended 31 December 2021: 271,046,179). 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

	Unaudited 30 June 2022 £	Unaudited 30 June 2021 £	Audited 31 December 2021 £
Amounts receivable within one year:			
Trade receivables	**7,547**	21,333	7,547
Other receivables	**12,137**	10,440	-
Financial assets	**19,684**	31,773	7,547
Prepayments and accrued income	**79,927**	51,977	71,709
	99,611	83,750	79,256

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

7. Cash and cash equivalents

	Unaudited 30 June 2022 £	Unaudited 30 June 2021 £	Audited 31 December 2021 £
Cash at bank and in hand	**6,676,249**	12,762,201	10,372,571
Sterling fixed rate short-term deposits	**-**	-	-
	6,676,249	12,762,201	10,372,571

8. Trade and Other Payables

	Unaudited 30 June 2022 £	Unaudited 30 June 2021 £	Audited 31 December 2021 £
Trade payables	**(414,860)**	(483,502)	(981,392)
Social security and other taxes	**(54,835)**	(43,926)	(281,766)
Deposit liability	**(369,584)**	-	(109,435)
Accrued expenses	**(549,551)**	(207,875)	(705,591)
	(1,388,830)	(735,303)	(2,078,184)

9. 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.

10. Taxation

The Group's tax credit in the six months ended 30 June 2022 was £0.35 million (six months ended 30 June 2021: £0.32m, year ended 31 December 2021: £0.91 million). The tax credit balance of £1.26 million relates to anticipated R&D tax credits in respect of claims not yet received/submitted for the 2021 and 2022 financial year.

11. Share Capital

Authorised	**30 June 2022 Number**	30 June 2021 Number	31 December 2021 Number	**30 June 2022 £**	30 June 2021 £	31 December 2021 £
Ordinary shares of 0.2 pence each	**500,000,000**	500,000,000	500,000,000	**1,000,000**	1,000,000	1,000,000

Allotted, called up and fully paid	**30 June 2022 Number**	30 June 2021 Number	31 December 2021 Number	**30 June 2022 £**	30 June 2021 £	31 December 2021 £
Ordinary shares of 0.2 pence each	**287,296,527**	287,070,971	287,150,971	**574,593**	574,142	574,302

11. Share Capital (continued)

The number of issued ordinary shares as at 1 January 2022 was 287,150,971 During the period of six months ended 30 June 2022, the Company issued 145,556 ordinary shares of 0.2 pence with each ordinary share carrying the right to one vote as follows:

		£	Number
January 2022	Non-Executive Director Share Award	21,834	145,556
		21,834	**145,556**

12. Subsequent events

There were no material post-period events.

Company number
04206001

Directors

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

Audit committee
Andrew Unitt
John Clarke

Remuneration committee
Jeff Needham
John Clarke
Andrew Unitt

Nominations committee
John Clarke
Jeff Needham
Andrew Unitt

Secretary and registered office
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