

FUTURA MEDICAL PLC 16 SEPTEMBER 2020

INTERIM RESULTS FOR THE SIX MONTHS ENDED 30 JUNE 2020

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 2020.

HIGHLIGHTS

MED3000 - a topical treatment for Erectile Dysfunction

- In February 2020 Futura commenced formal proceedings for MED3000 to be approved as a medical device and clinically proven treatment for ED in Europe by an EU Notified Body¹.
- The European regulatory process for MED3000 remains on track with the company targeting a 2021 European approval date.
- De Novo medical device status for MED3000 confirmed by US Food and Drug Administration (“FDA”) in February pre-submission meeting and Futura invited to pursue further pre-submission meeting once the Company was in receipt of the final clinical study report for FM57.
- Significant commercial opportunity with MED3000 as the first clinically proven treatment for erectile dysfunction likely to be available throughout the EU and USA without the need of a doctor’s prescription.

MED3000 - Post period highlights

- MED3000 product dossier for the treatment of erectile dysfunction (“ED”) submitted under the European Medical Device Regulation for marketing approval in mid-July.
- Positive audit opinion received for Futura’s Quality Management Systems (“QMS”) from the relevant EU Notified Body in the European approval process for MED3000; a key milestone in the EU approval process.
- Second pre-submission meeting held with FDA, confirming a requirement for supplementary data primarily consisting of a further small clinical study where patients with ED may receive MED3000 for a six-month treatment period with precise details to be confirmed at a third pre-submission meeting.
- Meeting set for the third pre-submission meeting with the FDA before the end of October.
- Futura has retained specialised corporate advisers with international experience to facilitate active commercial discussions with potential licensing and marketing partners and is actively pursuing discussions.

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

TPR100 - Post period events

- Completion of additional laboratory work required by the UK Medicines and Healthcare products Regulatory Agency (“MHRA”) to support the UK submission made by partner Thornton & Ross (a subsidiary of STADA AG).
- In conjunction with its commercial partner, Futura is seeking a scientific advisory meeting with the MHRA before year end to review data and confirm the exact pathway for approval.

CBD100 - Futura's advanced proprietary DermaSys® formulation for transdermal delivery of Cannabidiol

CBD100 Post period highlights

- Completion of initial laboratory and optimisation work on a DermaSys® cannabidiol gel (“CBD100”) under the joint venture collaboration agreement with CBDerma Technology Limited.
- Compelling in vitro data delivered with up to eight times greater delivery of cannabidiol into the skin with a DermaSys® gel formulation versus an established comparator product.
- Patent application submitted for the selected CBD100 novel formulation.

Financial highlights

- £1.06 million net loss in the period (30 June 2019: net loss £4.46 million).
- In May 2020, the company received R&D tax credits of £2.22 million from HMRC with respect to the year ending 2019.
- Cash resources of £2.62 million at 30 June 2020 (30 June 2019: £5.63 million).
- The company continues to have sufficient cash resources through to Q2 2021 under current plans.

COVID-19 Update

The impact of COVID-19 on the Company has been limited to date. Futura's virtual model has enabled effective and efficient home-working for all staff and all its external suppliers, including regulatory agencies and laboratories which continue to operate in line with its expectations and timelines. The safety of Futura's employees, third-party suppliers and partners remains the primary concern. The Company continues to follow the government guidance in regions in which it operates.

James Barder, Chief Executive of Futura, commented: "Futura is in the late stages of regulatory procedures to bring MED3000 to market for erectile dysfunction. Importantly, we have completed the audits and submissions for a European review of the product under the new Medical Device Regulations and are targeting an approval of MED3000 in 2021. A meeting has been arranged with the FDA before the end of October 2020, where we expect to agree the final outstanding data requirements to gain regulatory approval for MED3000 as an OTC² treatment in the USA.

“We are increasingly excited by the commercial potential for MED3000 as the first, clinically proven treatment for erectile dysfunction that is highly differentiated with its rapid speed of onset and may be available without the need of a doctor’s prescription bringing accessibility to men throughout the EU and USA. This sentiment is shared with a number of potential commercial partners with whom we are now actively engaged in discussions.”

1. *A Notified Body is an organisation designated by EU regulators to assess the conformity of medical devices before being placed on the market*
2. *An Over the Counter (“OTC”) treatment can be purchased without the need of a doctor’s prescription*

OPERATIONAL REVIEW - “EXECUTING ON STRATEGIC PLANS TO LEVERAGE DERMASYS®”

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.

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 - Topical gel for erectile dysfunction (“ED”)

MED3000 is a formulation of the proprietary technology DermaSys®, for the treatment of ED. MED3000 has the potential to be a highly differentiated product by addressing significant unmet needs, across all patient severities in the \$5.6 billion ED market¹, which include rapid speed of onset enabling spontaneity for both partners, significant clinical benefits alongside excellent safety and low side effects and no interactions with alcohol or food as well as providing a potential treatment option for patients contra-indicated from using existing ED therapies. As such it has the potential to become the first globally available, clinically proven, over the counter (“OTC”) treatment for erectile dysfunction.

ED disrupts the lives of at least 1 in 5 men globally², 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, a statement frequently made by Key Opinion Leaders in the field of sexual medicine.

Top line results from the Phase 3 FM57 study announced in December 2019, demonstrated that MED3000 has the potential to be a highly effective, clinically proven, topical treatment for ED, with a fast onset of action. As part of FM57, the Company observed that MED3000 began to work immediately in some patients, with 60% of patients seeing onset of their erection within 10 minutes of application. Company and external research indicate MED3000's combination of volatile solvent components creates an evaporative and novel action that stimulates nerve sensors in the highly innervated glans penis rapidly leading to smooth muscle relaxation, tumescence and erection.

Overall, the level of efficacy was broadly equivalent to lower doses of current oral ED treatments and substantially higher than placebo effects typically seen with ED treatments³. In addition, the adverse events were significantly lower than seen with oral ED treatments. This excellent safety profile, together with a rapid speed of onset and good efficacy creates a substantial and highly competitive product opportunity for MED3000 as a medical device for ED with the potential for OTC use bringing a new and accessible treatment option for patients.

MED3000 - Medical Device Regulatory Pathway

Europe

The Company announced in February 2020, following positive interactions with an EU Notified Body, that it had commenced formal proceedings for MED3000 in Europe.

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

The company announced in mid-July that it had submitted the product dossier for MED3000 for treatment of ED under the European Medical Device Regulation for marketing approval as a Class 2B medical device. The dossier included the clinical study report for FM57 and technical specifications of the Company's Quality Management System.

Following this, in early August, the company announced that it had received a positive audit opinion for its QMS from the relevant EU Notified Body. Futura's QMS thus meets the required standard for the new MDR and the positive audit opinion paves the way for the Notified Body to complete its review of the technical documentation. Futura continues to target a 2021 European approval date for MED3000.

US

Initial presentation of existing clinical evidence from the MED3000 FM57 phase 3 study was made at a US Food and Drug Administration (“FDA”) pre-submission meeting in late February 2020.

Following receipt of the formal meeting minutes from the first pre-submission meeting in early April, the FDA agreed to a De Novo medical device application for MED3000 and invited Futura to pursue another pre-submission meeting once the Company was in receipt of the final clinical study report for FM57.

In mid-July the company announced that a second pre-submission meeting with the FDA had taken place. As a result of this the Board believes a pathway to a marketing approval for MED3000 in the USA has been established, and importantly, without the need for a doctor's prescription. Furthermore the recent receipt of the formal meeting minutes for the second pre-submission meeting continues to support the Company's belief. None of the market leading treatments for ED, such as Viagra® and Cialis®, are currently approved in the USA without the need of a doctor's prescription and therefore MED3000 will meet the needs of the majority of consumers who would prefer to treat their ED without having to obtain a prescription.

During the meeting the FDA indicated a requirement for certain supplementary clinical efficacy data beyond the FM57 phase 3 study completed in 2019. This additional data will likely require a further small clinical study where patients with ED may receive MED3000 for a six-month treatment period. Futura is working proactively with the FDA to confirm design of the new clinical trial to provide the necessary reassurance of MED3000's efficacy for up to six months and progress the OTC label and leaflet development. This requirement to run a small confirmatory study of 6 month's duration in addition to the completed large pivotal study, FM57 is significantly less burdensome than two large pivotal studies that would have been required as a drug product as opposed to a medical device. Final clearance from the FDA on the scope and design of the additional study will allow Futura to determine the expected cost. Futura expects to give a progress update following the third pre-submission meeting with the FDA rescheduled before the end of October and ahead of the commencement of any additional study which start will be dependent upon such FDA clearance.

MED3000 Commercialisation plans

In parallel with the regulatory processes and executing upon strategic plans, Futura has retained specialised corporate advisers with international experience to facilitate active commercial discussions with potential licensing and marketing partners.

Around 50% of men with ED do not discuss their condition with their doctor⁴ which represents a significant untapped commercial opportunity for a clinically proven treatment with OTC status in the USA and EU. Despite efforts over many years from major pharmaceutical companies to switch current drug treatments for ED from requiring a doctor's prescription to OTC, the number of OTC approvals remains limited. In 2018 the MHRA approved a switch for Viagra Connect[®] (Pfizer) in the UK, being one of only three countries currently within the EU where Viagra[®] has such OTC status. No switch of any oral ED treatment has been approved by the FDA in USA currently. Barriers to OTC include drug-related adverse events and potentially dangerous interactions with other drugs neither of which present an issue with MED3000 because of its drug-free mode of action.

TPR100 – 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.

Additional laboratory work required by the MHRA to support the UK submission made by Thornton & Ross continued in H1 2020 and has now concluded. The results continue to underline the strength of the DermaSys[®] technology in enabling controlled and targeted permeation of diclofenac through the skin. In conjunction with its commercial partner, Futura is seeking a scientific advisory meeting with the MHRA before year end to review the data re-establish regulatory clarity around the exact pathway for approval and any outstanding additional requirements.

Commercial discussions with several potential distribution partners for other countries continue and any further licensing deals are expected to be after UK regulatory approval.

CBD100 - Futura's advanced, proprietary DermaSys[®] formulation for transdermal delivery of Cannabidiol

CBD100 is part of a joint venture collaboration with CBDerma Technology Limited signed in September 2019 and aiming to explore the application of Futura's advanced proprietary transdermal drug delivery technology, DermaSys[®] for delivery of Cannabidiol.

CBDerma Technology is a company that was established and funded to specifically exploit the therapeutic potential of Cannabis. Cannabidiol is a major component of the cannabis plant and is generally regarded as non-addictive and non-psychoactive, making it ideal for consideration as a topically delivered molecule for local or regional (non-systemic) use. The market for Cannabidiol products is growing rapidly. A report by Reports and Data forecasts that the market for Cannabidiol products is forecast to grow from \$1bn in 2018 to \$16bn by 2026, at a CAGR of 27.7%, during the forecast period. The market is primarily driven by the increase in the usage of Cannabidiol in medical applications and cosmetics such as supplements, beverages and skin care.

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

As part of a robust formulation process using strict pharmaceutical development principles, Futura carried out extensive DermaSys® cannabidiol formulation work and initial in vitro tests on human epidermis. The studies demonstrated highly efficient penetration of cannabidiol into and through the skin, superior to an established, marketed, comparator product. Additionally, cannabidiol is known to be unstable with many common excipients. CBD100 was specially formulated to minimise this issue and has shown encouraging early stability work, which is expected to ensure potency is retained during shelf-life.

An intellectual property filing has now been made covering various unique aspects of the CBD100 gel formulation.

Futura is in discussions with its joint venture partner over both the next steps from a development and also commercial standpoint. A gel that has been formulated using strict pharmaceutical development principles with strong delivery characteristics, stability and high quality could be a very attractive commercial proposition when compared to current market incumbents in either cosmetic or more traditional pharmaceutical markets for cannabidiol such as pain and inflammation. Both options are being examined.

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

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

1. *Manufacturers' Selling Prices 2018: Data available for 75 countries IQVIA IMS Health*
2. *EMA, Withdrawal assessment report for Viagra, 2008*
3. *Araujo AC et al: The Management of Erectile Dysfunction with Placebo Only: Does it work J Sex Med 6:3440-3448; 2009*
4. *Rosen Curr Med Res Opin. 2004 May;20(5):607-17*

FINANCIAL REVIEW

Research and Development Costs

Research and Development costs for the six months ended 30 June 2020 were £0.93 million, compared to £4.74 million for the six months ended 30 June 2019.

Administrative Costs

Administrative costs were £0.47 million for the six months ended 30 June 2020 compared to £0.53 million for the six months ended 30 June 2019 and were reflective of the Company's strategy to keep central costs lean.

Going Concern

At the period end the Group held £2.62 million of cash. The Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

Taxation

In May 2020, the company received R&D tax credits of £2.22 million from HMRC with respect to the year ending 2019. The company continues to have sufficient cash resources through to Q2 2021 under current plans.

Outlook

We are excited to be moving through the late-stage regulatory processes for bringing MED3000, an innovative, highly differentiated ED product to market that could help the many ED patients whose needs are not met by current treatments.

Importantly, in Europe, we have completed technical dossier submissions and received a positive QMS audit that paves the way for the EU notified body to complete its review of the product. Futura continues to target a 2021 European approval date for MED3000. In the USA, where the regulatory process is an ongoing and iterative process we are working positively with FDA to define the additional small study design required to confirm clinical efficacy and expect to be able to provide a progress update including the likely cost of such a study once the design has been agreed in the coming months. In both Europe and USA the Board believes MED3000 has a path to approval as a clinically proven treatment for ED which is available without the need of a doctor's prescription. This OTC status would be a first in the USA and also for the majority of countries within the EU providing patients with an accessible, new treatment option, for their ED.

In parallel we are actively pursuing commercial licensing options for MED3000 and managing the Company's resources prudently whilst planning and building for the future to further leverage our DermaSys® technology and products in pain relief and for the delivery of cannabidiol.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the six months ended 30 June 2020

		Unaudited 6 months ended 30 June 2020	Unaudited 6 months ended 30 June 2019	Audited year ended 31 December 2019
	Notes	£	£	£
Revenue		-	-	31,778
Research and development costs		(926,802)	(4,739,965)	(10,051,148)
Administrative costs		(466,065)	(534,545)	(1,144,397)
Operating loss		(1,392,867)	(5,274,510)	(11,163,767)
Finance income		938	13,395	22,283
Loss before tax		(1,391,929)	(5,261,115)	(11,141,484)
Taxation	10	330,000	800,000	2,222,194
Total comprehensive loss for the period attributable to owners of the parent company		(1,061,929)	(4,461,115)	(8,919,290)
Loss per share (pence)	5	(0.44p)	(2.18p)	(4.36p)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2020

	Notes	Unaudited 30 June 2020 £	Unaudited 30 June 2019 £	Audited 31 December 2019 £
Assets				
Non-current assets				
Plant and equipment		51,350	71,800	59,505
Total non-current assets		51,350	71,800	59,505
Current assets				
Inventories		7,780	7,780	7,780
Trade and other receivables	6	64,871	122,887	101,192
Current tax asset		329,712	2,158,192	2,222,194
Cash and cash equivalents	7	2,615,085	5,626,792	2,510,501
Total current assets		3,017,448	7,915,651	4,841,667
Liabilities				
Current liabilities				
Trade and other payables	8	(950,432)	(3,535,304)	(4,847,520)
Total liabilities		(950,432)	(3,535,304)	(4,847,520)
Total net assets		2,118,366	4,452,147	53,652
Capital and reserves attributable to owners of the parent company				
Share capital	11	491,254	409,321	409,321
Share premium		52,814,090	50,002,990	50,002,990
Merger reserve		1,152,165	1,152,165	1,152,165
Warrant Reserve	11	165,868	-	-
Retained losses		(52,505,011)	(47,112,329)	(51,510,824)
Total equity		2,118,366	4,452,147	53,652

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the six months ended 30 June 2020

	Share Capital £	Share Premium £	Merger Reserve £	Warrant Reserve £	Retained Losses £	Total Equity £
At 1 January 2019 - audited	409,167	49,983,860	1,152,165	-	(42,692,938)	8,852,254
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
<i>Transactions with Owners</i>	<i>154</i>	<i>19,130</i>	<i>-</i>	<i>-</i>	<i>41,724</i>	<i>61,008</i>
At 30 June 2019 - unaudited	409,321	50,002,990	1,152,165	-	(47,112,329)	4,452,147
Total comprehensive loss for the period	-	-	-	-	(4,458,175)	(4,458,175)
Share-based payment	-	-	-	-	59,680	59,680
Shares issued during the period	-	-	-	-	-	-
<i>Transactions with Owners</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>59,680</i>	<i>59,680</i>
At 31 December 2019 - audited	409,321	50,002,990	1,152,165	-	(51,510,824)	53,652
Total comprehensive loss for the period	-	-	-	-	(1,061,929)	(1,061,929)
Share-based payment	-	-	-	-	67,742	67,742
Shares issued during the period	81,933	2,811,100	-	165,868	-	3,058,901
<i>Transactions with Owners</i>	<i>81,933</i>	<i>2,811,100</i>	<i>-</i>	<i>165,868</i>	<i>67,742</i>	<i>3,126,643</i>
At 30 June 2020 - unaudited	491,254	52,814,090	1,152,165	165,868	(52,505,011)	2,118,366

CONSOLIDATED STATEMENT OF CASH FLOWS

For the six months ended 30 June 2020

	Unaudited 6 months ended 30 June 2020 £	Unaudited 6 months ended 30 June 2019 £	Audited year ended 31 December 2019 £
Cash flows from operating activities			
Loss before tax	(1,391,929)	(5,261,115)	(11,141,484)
Adjustments for:			
Depreciation	12,353	7,860	20,704
Loss on disposal of fixed assets	-	-	-
Finance income	(938)	(13,395)	(22,283)
Share-based payment charge	67,742	41,724	101,404
Cash flows from operating activities before changes in working capital	(1,312,772)	(5,224,926)	(11,041,659)
Decrease in inventories	-	-	-
(Increase) / decrease in trade and other receivables	36,321	183,522	204,928
(Decrease) / increase in trade and other payables	(3,897,088)	1,509,788	2,822,004
Cash used in operations	(5,173,539)	(3,531,617)	(8,014,727)
Income tax received	2,222,194	-	1,358,480
Net cash used in operating activities	(2,951,345)	(3,531,617)	(6,656,247)
Cash flows from investing activities			
Purchase of plant and equipment	(3,910)	(32,186)	(32,736)
Interest received	938	13,395	22,283
Cash (used in) / generated by investing activities	(2,972)	(18,791)	(10,453)
Cash flows from financing activities			
Issue of ordinary shares	3,270,533	19,284	19,284
Expenses paid in connection with share issues	(211,632)	-	-
Cash generated by financing activities	3,058,901	19,284	19,284
(Decrease) / increase in cash and cash equivalents	104,584	(3,531,124)	(6,647,415)
Cash and cash equivalents at beginning of period	2,510,501	9,157,916	9,157,916
Cash and cash equivalents at end of period	2,615,085	5,626,792	2,510,501

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2020

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, 2020 were authorised for issue in accordance with a resolution of the Directors on 15th September, 2020. 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 2019, 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 2020 and for the six months ended 30 June 2019 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 2019 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 2019 and does not constitute the full statutory accounts for that period. The Annual Report for 2019 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 2020 of £1.06 million (six months ended 30 June 2019: £4.46 million, year ended 31 December 2019: £8.92 million). The Group holds cash balances of £2.62 million at 30 June 2020 (30 June 2019: £5.63 million, 31 December 2019: £2.51 million).

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2020

The 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 result and cashflow forecasts for the 12 months' period following the date of signing the financial statements. Under current business plans which has assumed a significant reduction in R&D spend, the Group's cash resources will extend to Q2 2021. Based on this, additional funding is expected to be required to support the Group's and the Company's going concern status. The Directors have a reasonable expectation that the Group will be able to access further funding, which could come from a variety of dilutive and non-dilutive sources, to support its ongoing activities. The Directors also have a reasonable expectation that the Group will be able to generate significant funding through entering into strategic collaborations for the commercialisation of MED3000 and its other products in the US and Europe.

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

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, the above factors give rise to a material uncertainty which may cast significant doubt on the Group's and 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 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 £67,742 for the six months ending June 2020 (six months ended 30 June 2019: £41,724, year ended 31 December 2019: £101,404), 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 2020 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.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2020

4. Segment reporting

The Group is organised and operates as one segment. The Group's external R&D costs are analysed by development programme as follows:

	Unaudited 30 June 2020 £	Unaudited 30 June 2019 £	Audited 31 December 2019 £
MED	154,144	3,783,800	8,019,710
TPR	33,885	66,545	230,639
Other	(156,904)	34,351	224,592
	31,125	3,884,697	8,474,941

5. Loss per share (pence)

The calculation of the loss per share is based on a loss of £1,061,929 (six months ended 30 June 2019: loss of £4,461,115; year ended 31 December 2019: loss of £8,919,290) and on a weighted average number of shares in issue of 241,794,738 (six months ended 30 June 2019: 204,655,173; year ended 31 December 2019: 204,657,741). 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 2020 £	Unaudited 30 June 2019 £	Audited 31 December 2019 £
Amounts receivable within one year:			
Trade receivables	5,627	627	5,627
Other receivables	10,440	63,604	54,341
Financial assets	16,067	64,231	59,968
Prepayments and accrued income	48,804	58,656	41,224
	64,871	122,887	101,192

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.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2020

7. Cash and cash equivalents

	Unaudited 30 June 2020 £	Unaudited 30 June 2019 £	Audited 31 December 2019 £
Cash at bank and in hand	2,241,367	2,162,364	2,137,599
Sterling fixed rate short-term deposits	373,718	3,464,428	372,902
	2,615,085	5,626,792	2,510,501

8. Trade and Other Payables

	Unaudited 30 June 2020 £	Unaudited 31 December 2019 £	Audited 31 December 2019 £
Trade payables	381,838	2,625,359	1,246,247
Social security and other taxes	56,142	39,970	42,684
Deferred Income	-	218,222	-
Accrued expenses	512,452	1,963,969	736,584
	950,432	4,847,520	2,025,515

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 2020 was £0.3 million (six months ended 30 June 2019: £0.8m, year ended 31 December: £2.22 million). The current period tax credit relates to anticipated R&D tax credits in respect of claims not yet submitted for the 2020 financial year.

NOTES TO THE CONSOLIDATED INTERIM FINANCIAL STATEMENTS

For the six months ended 30 June 2020

11. Share Capital

	30 June 2020 Number	30 June 2019 Number	31 December 2019 Number	30 June 2020 £	30 June 2019 £	31 December 2019 £
Authorised						
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

	30 June 2020 Number	30 June 2019 Number	31 December 2019 Number	30 June 2020 £	30 June 2019 £	31 December 2019 £
Allotted, called up and fully paid						
Ordinary shares of 0.2 pence each	245,626,926	204,583,439	204,660,267	491,254	409,167	409,321

The number of issued ordinary shares as at 1 January 2020 was 204,660,267. During the period of six months ended June 2020, the Company issued shares of 0.2 pence with each ordinary share carrying the right to one vote as follows:

		£	Number
January 2020	Subscription and Primary Bid Offer	3,250,000	40,625,000
January 2020	Non-Executive Director Share Award	20,500	341,659
		3,270,500	40,966,659

In January 2020, Futura Medical plc issued a warrant instrument as part of a wider share issue to raise funds under a conditional subscription agreement and a Primary Bid Offer. An Investor agreed to subscribe to 21,875,000 Ordinary Shares and a total of 10,937,500 warrants were issued. These warrants have been valued using the Black-Scholes model and its value has been bifurcated alongside the value of shares issued. A warrant reserve of £165,868 has therefore been recognised.

12. Subsequent events

There were no material post-period events.

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

Angela Hildreth
Futura Medical plc
Surrey Technology Centre
40 Occam Road
Guildford
Surrey
GU2 7YG

Auditors

Grant Thornton
1020 Eskdale Road
Winnersh
Wokingham
Berkshire
RG41 5TS

Registrars

Link Asset Services
34 Beckenham Road
Beckenham
Kent
BR3 4TU

Nominated adviser and broker

Liberum
25 Ropemaker Street
London
EC2Y 9LY

Patent attorneys

Withers & Rogers LLP
4 More London Riverside
London
SE1 2AU

Public relations advisers

Optimum Strategic
Communications
Warnford Court
29 Throgmorton Street
London
EC2N 2AT

Principal solicitors

Square One Law
Anson House
Fleming Business Centre
Burdon Terrace,
Jesmond
Newcastle upon Tyne
NE2 3AE

Principal bankers

HSBC Bank
12A North Street
Guildford
GU1 4AF

Investment managers

Royal London Asset
Management Limited
PO Box 9035
Chelmsford
CM99 2XB