FUTURA MEDICAL PLC
29 SEPTEMBER 2021

INTERIM RESULTS FOR THE SIX MONTHS ENDED 30 JUNE 2021

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 and currently focused on sexual health and pain, is pleased to announce its interim results for the six months ended 30 June 2021.

HIGHLIGHTS

Europe

- Significant progress made in Europe and the UK with the Company receiving its MDR EU Quality Management Certificate in April 2021, for placing MED3000 on the market as a Class 2B medical device also known as European "CE mark approval".
- Futura's breakthrough, topical gel formulation MED3000, will become the first pan-European topical treatment for erectile dysfunction ("ED") available without the need of a doctor's prescription ("OTC").

USA

- Further pre-submission meetings with the US Food and Drug Administration (FDA) held during the period to finalise the design of a small supplemental clinical trial (known as "FM71") to be conducted prior to formal regulatory submission as a DeNovo Medical Device and a Human Factors study required by FDA for OTC marketing approval of MED3000 in USA.
- In March 2021 the Company received official minutes from the FDA following the pre-submission meeting signifying agreement between FDA and Futura on the detailed clinical study design (protocol) for clinical study, FM71.

USA – Post period highlights

- In August 2021 Futura received final meeting minutes from a July 2021 pre-submission meeting with FDA that also confirmed the detail of the work required for OTC classification in the USA for MED3000.
    - To enable OTC classification a non-clinical, Human Factors Study will test the ability of subjects to self-diagnose their ED, correctly select the product based on label information and test their ability to correctly use the product without supervision of a doctor. The FDA has asked for a minimum of 15 subjects to complete the study.
- On 14 September 2021 the first patient was enrolled in the FM71 confirmatory clinical study.

- Both the Human Factors and FM71 studies are now progressing in line with plans to submit MED3000 for US regulatory approval as a DeNovo medical device for ED treatment, with OTC classification by end Q3 2022.
- US marketing authorisation remains on track for potential approval of MED3000 in Q1 2023.

Commercial

- Futura aims to create 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 across the globe.
- Joint collaboration agreement for China and South East (SE) Asia with 50/50 share of profits signed in March 2021. Discussions are being held with the Chinese regulator, the National Medical Products Administration (NMPA), to clarify scope of clinical work required to gain approval in China. Expected additional R&D costs of up to £4 million are being fully met by our partner. In a number of additional SE Asian markets Futura is also working on nearer term regulatory submissions.

Commercial - Post period highlights

- In August 2021 Futura entered into a licensing agreement with m8 Pharmaceuticals, Inc ("m8"), a specialty biopharmaceutical company focused on commercialisation in Latin America, for the rights to exclusively develop and commercialise the Company's MED3000, in Brazil and Mexico.
- In September 2021 Futura signed a licensing agreement with Labatec Pharma (“Labatec”), a Swiss-based specialty pharma Company with expertise in commercialisation in Europe and the Middle East North Africa (“MENA”) region for exclusive rights to commercialise MED3000 in the Gulf Co-operation (“GCC”) region, Jordan, Lebanon and Iraq.
- MED3000 manufacturing capabilities expanded in August with addition of a new third party, FDA, EMA and UK approved manufacturer as Futura strengthens resources in the build up towards product launches in 2022.

Financial highlights

- In May 2021 the Company conducted a £12 million (net) fundraise including retail offer.
- £1.59 million net loss in the period (30 June 2020: net loss £1.06 million).
- Cash resources of £12.76 million at 30 June 2021 (30 June 2020: £2.62 million).
- Current cash runway extends beyond expected initial MED3000 launches in 2022 and expected US regulatory approval.

COVID-19

The impact of COVID-19 on the Company has been limited to date. The safety of our employees, third-party suppliers and partners remains our primary concern, and we have continued to follow the government guidance in regions in which we operate.

James Barder, Chief Executive of Futura, commented: "Futura is in the late stages of regulatory procedures to bring MED3000 to market for erectile dysfunction in the key US market and is targeting US submission by end Q3 2022. After CE mark approval by the European regulator the Company is preparing for first product launches during 2022 not just in Europe but also countries where recognition of the CE mark may allow “fast-track” review, importantly making a highly differentiated treatment option accessible and available to patients without a doctor’s prescription.

We are furthermore proud of having achieved important milestones in terms of securing partnering for the development and commercialisation of MED3000 in additional major markets for erectile dysfunction, including China, South East Asia, Latin America, the Gulf and Middle East in deals structured to capture significant long-term value, as well as the EU Notified Body's recommendation to certificate MED3000 for Class 2B approval as a medical device for ED treatment under the European Medical Device Regulations."

"The Company is well positioned to deliver further positive news through the remainder of 2021 and in 2022 as we drive towards MED3000 2022 product launches, a global product franchise and our objective to deliver a long-term and sustainable revenue for shareholders."

OPERATIONAL REVIEW - "SIGNIFICANT PROGRESS IN MED3000 COMMERCIALISATION AS PREPARATIONS MADE FOR LAUNCHES STARTING 2022"

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 multi-billion dollar ED market[1], 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. It has the potential to become the first globally available, clinically proven, over the counter ("OTC") treatment for erectile dysfunction and has already been approved as the first pan-European topical treatment for ED available without the need of a doctor's prescription.

The prevalence of ED disrupts the lives of at least 1 in 5 men globally[2], with around 23 million men in the US and 20 million men in the UK, France, Italy and Germany. Whereas there has been little innovation in ED treatments for over ten years and many patients continue to suffer dissatisfaction with existing treatments the market continues to evolve especially within the USA with the advent of subscription services such as For Hims and Get Roman, and also in the UK with Numan which offers a branded concierge service for ED prescription medicines online. These subscription services offer a monthly subscription fee, typically in the region of US$50 in return for a doctor's consultation and ten generic 50mg sildenafil tablets per month. This increased affordability of around US$5 per tablet (to the end user) is driving volumes especially in the USA which have increased by 85% between 2018 and 2020[1].

MED3000 - Medical device regulatory pathways

Europe

In April 2021 the Company announced that it 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"). 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 ("OTC").

Studies have shown MED3000 to be an extremely 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, substantially faster than on-demand oral tablet phosphodiesterase-5 inhibitors (PDE5i's), with significant benefits for spontaneous rather than pre-planned sexual intercourse.

The CE mark approval of MED3000 from the EU Notified Body paves the way for approval in many countries around the world, including in the Middle East, Africa and the Far East regions which allow "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. This will be a streamlined process since it is understood the UK application can bridge to the EU approval.

USA

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

Summarising US activity to date in 2021

In March 2021 Futura announced that it received official minutes from the US Food and Drug Administration (FDA) for MED3000, following its Pre-Submission Meeting on 1 February 2021 confirming agreed design for the confirmatory FM71 clinical trial.

In July 2021 Futura met with the FDA for a pre-submission meeting to define and confirm the detail of the work required for OTC classification in the USA for MED3000. This was confirmed when final meeting minutes were issued in August 2021. The short, non-clinical, “Human Factors” study will test the ability of subjects to self-diagnose their ED, correctly select the product based on label information and test their ability to correctly use the product without supervision of a doctor. The FDA has asked for a minimum of 15 subjects to complete the study.

On 15 September 2021 Futura announced that the first patient had entered pre-screening in FM71. The Human Factors study is running in parallel with FM71 to enable planned regulatory submission by end of Q3 2022. Therefore, US OTC marketing authorisation remains on track for potential approval of MED3000 in Q1 2023.

US confirmatory clinical study, FM71

FM71 is designed as a Phase 3, multicentre, comparative, randomised, open-label, home use, parallel group study to provide supplementary efficacy data to the previously reported FM57 study with a "least burdensome" approach and modest cost, estimated to be £3 million. Whilst the overall design is similar to that of the previous large Phase 3 FM57 study that recruited approximately 1,000 patients, no placebo (sham) cohort is required, hence the study is relatively smaller in size with approximately 100 patients. The recruited patients will include those suffering from mild, moderate or severe ED, using either MED3000 or tadalafil 5mg (50 subjects per group) and will also include 20 African American patients (from a US medical centre)

and 80 patients recruited from Eastern Europe where sites include some of the same centres used in the FM57 study.

FM71 will be a 7-month study (including 1 month to establish baseline), studying 6-month (24 weeks) treatment duration versus FM57 which was conducted over 3 months' treatment duration (12 weeks) to reassure the FDA that the efficacy does not diminish over a longer period of time. It is Futura's belief that this is unlikely as in the FM57 study, efficacy improved from the first to third month of patient use. Two co-primary endpoints will measure the change from baseline, and whether this change is clinically meaningful using the Rosen statistical method, a standard assessment technique for measuring Patient Reported Outcomes. Both these end points were measured in FM57 at 12 weeks and were met and exceeded the stated criteria. Secondary endpoints include an agreed measure of speed of onset, a key differentiating claim, where FM57 showed that 60% of subjects noticed an erection within 10 minutes.

The Company has agreed with the FDA to include tadalafil (the active in Cialis®) at the lowest approved dose for on-demand use (5mg) for comparative purposes only on safety, speed of onset and efficacy. Non-inferiority is not required to be shown.

MED3000 commercialisation

In early March 2021 Futura announced investment into the Company and joint collaboration with Co-High Investment Management Limited and certain subsidiaries of Atlantis Group to commercialise MED3000 in China and South East Asia. Futura also announced in August 2021 that it entered into a licensing agreement with m8 Pharmaceuticals to commercialise MED3000 in Brazil and Mexico, swiftly followed in September by a licensing agreement with Labatec Pharma ("Labatec") for exclusive rights to commercialise MED3000 in the Gulf Co-operation ("GCC") region, Jordan, Lebanon and Iraq.

Co-High licensing agreement - China and South East Asia

In March 2021 Futura entered into £1.5 million convertible debt and £0.5 million of warrants financing transactions with HT Riverwood Multi-Growth Fund ("Riverwood"), a fund managed by Atlantis Investment Management Limited ("Atlantis"), which provided the Company with £2 million in cash. These financial instruments were respectively converted and exercised by Riverwood in March and April 2021 and there are no further amounts outstanding to Riverwood from Futura.

Atlantis is a 100% owned subsidiary of the Atlantis Group and Co-High Investment Limited ("Co-High) is a 60% owned subsidiary of the Atlantis Group. Ms Yang Liu, now Atlantis' Chairperson and Chief Investment Officer, acquired the Atlantis Group in 2009.

Additionally, Futura entered into a licensing agreement with Pride Century Ventures, a special purpose vehicle owned by Co-High for the rights to exclusively develop and commercialise the Company's topical, gel-based ED treatment MED3000, in China and South East Asia (the "Region"). Co-High will provide funding currently estimated to be up to £4 million for the expected remaining R&D work required to gain approval of MED3000 throughout the Region. Futura will be entitled to 50% of profits from the commercialisation of MED3000 within the Region (the "Joint Collaboration") including any profits derived from local partner agreements within the Region.

Atlantis is a leading international asset management company with a focus in the Greater China Region and South East Asia. Co-High is a specialist private equity company in the Greater China region and invests into and collaborates with some of the world's most promising companies which are believed to be poised to enter a hypergrowth phase. Healthcare investment and collaboration is targeted at companies with a clear scientific edge who are working to solve the major unmet medical needs of the Greater China region.

Under the terms of the agreement, Futura and Co-High will work together to develop and commercialise MED3000 as a clinically proven OTC treatment for ED throughout South East Asia.

Discussions are being held with the Chinese regulator, the National Medical Products Administration (NMPA), to clarify scope of clinical work required to gain approval in China. Current expectations are that a Chinese clinical trial will be required to establish safety as well as efficacy in Chinese men. Futura and Co-High are also working on additional South East Asian regulatory submissions, where CE mark designation is recognised, and may result in regulatory approval during 2022 following Futura's first launch for MED3000.

m8 Pharmaceuticals – Brazil and Mexico

In August 2021 Futura entered into a licensing agreement for MED3000 with m8 Pharmaceuticals, Inc ("m8"), a specialty biopharmaceutical company focused on commercialisation in Latin America, for the rights to exclusively develop and commercialise MED3000, in Brazil and Mexico.

Under the terms of the agreement Futura and m8 will work together to gain marketing authorisation and commercialise MED3000 as a clinically proven treatment for ED available without the need for a doctor's prescription ("OTC") in Brazil and Mexico, the two biggest countries and healthcare markets in Latin America. The agreement is for an initial term of 15 years.

m8 will be responsible for all costs related to the regulatory approval and marketing of the product. Futura will provide reasonable ongoing technical support for OTC product development and commercialisation. Futura will receive payments on all sales of MED3000 from m8, and up to four milestone payments totalling US$8.5 million based on cumulative sales volumes within the initial term.

Labatec – Gulf Co-operation Council ("GCC") region and Middle East

In September 2021 Futura entered into a licensing agreement with Labatec Pharma ("Labatec"), a Swiss-based specialty pharma Company focused on commercialisation in Europe and the Middle East and North Africa ("MENA") regions, for the rights to exclusively commercialise MED3000 in the GCC region as well as Jordan, Lebanon and Iraq.

Futura is eligible to receive initial upfront payments, as well as undisclosed milestone payments based on regulatory approval. Labatec will pay an agreed price to Futura for the manufacture and supply of MED3000 by Futura's Contract Manufacturing Organisation, plus royalties on all sales. Labatec is responsible for all local MED3000 development and regulatory costs as well as all launch and marketing expenses. The initial licence agreement term is for 8 years with the ability to extend for successive two-year terms by mutual consent.

MED3000 manufacturing and other commercialisation plans

Manufacturing scale up and capacity to meet projected demand is progressing well with, in August, the addition of a new, FDA, EMA and UK approved contract manufacturer as Futura strengthens resources in the build up towards MED3000 product launches in 2022.

Futura is making steady progress on commercial out-licensing agreements covering other major regions and countries of the world with several interested parties. The Company looks forward to providing further updates in the coming months.

Futura is committed to prioritising commercial deals that will deliver long-term and sustainable value to the Company allowing a long-lasting growth franchise to be built around the pipeline of DermaSys® formulated products and in particular MED3000. Futura aims to create 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 across the globe.

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.

A scientific advisory meeting was held with the Medicines and Healthcare products Regulatory Agency ("MHRA") confirming the need of a Phase 3 study to support the improved skin permeation and potential potency of TPR100 including potential superior efficacy claims.

Futura is exploring the feasibility of a clinical study that would satisfy the Phase 3 requirements for both UK and USA marketing approval. However, this will require a US distribution partner prior to the commencement of any Phase 3 programme.

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

CBD100 is part of a joint venture collaboration with CBDerma Technology Limited 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 US$1 billion in 2018 to US$16 billion by 2026, at a CAGR of 27.7%, during the forecast period. The market is primarily driven by the increase in the usage of cannabidiol in medical applications and cosmetics such as supplements, beverages and skin care.

Futura's extensive DermaSys® cannabidiol formulation work has 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. This work resulted in robust intellectual property filings covering various unique aspects of the CBD100 gel formulation.

As the medical and consumer applications of cannabidiol become more and more accepted and the regulatory environment becomes ever clearer a gel that has been formulated using strict pharmaceutical development principles with strong delivery characteristics, stability and high quality continues to 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 and Futura continues to explore commercial opportunities for the product.

Board update

As the Company moves towards the 2022 launch of MED3000 the Board considers this is the appropriate time to make several changes. Jonathan Freeman has been on the Board since the IPO in 2003 and will be stepping down as Senior Independent Non-Executive Director at the end of 2021. His contribution and support to the Company has been huge over many years and the Board is unanimous in thanking him for all his efforts.

In a planned process, management are also working towards strengthening the Company's Board with the appointment of Non Executive Directors with additional commercial expertise as Futura moves into the next phase of MED3000's commercialisation. These additions are expected to be announced shortly when the recruitment process completes.

References

1. *IQVIA IMS Health*
2. *EMA, Withdrawal assessment report for Viagra, 2008*

FINANCIAL REVIEW

Research and development costs

Research and Development costs for the six months ended 30 June 2021 were £1.19 million, compared to £0.93 million for the six months ended 30 June 2020.

Administrative costs

Administrative costs were £0.71 million for the six months ended 30 June 2021 compared to £0.47 million for the six months ended 30 June 2020 and were reflective of the Company's strategy to maintain a tight central cost base with the slight increase relating to one-off legal and professional costs totalling approximately £150,000 associated with the funding transactions and which do not meet the requirements for capitalisation.

Going concern

At the period end the Group held £12.76 million of cash. 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 in 2022 and expected US regulatory approval. The current runway does not include any revenues from commercial upfront milestones, royalties or other income generated from MED3000 sales.

OUTLOOK

The fund raise earlier in the year was pivotal in terms of strengthening the Company's finances and commercial negotiating positions and the last nine months have seen Futura achieve considerable milestones both in the evolution of the Company as it approaches a sustainable revenue stream and in terms of bringing MED3000 to patients suffering from erectile dysfunction and lacking treatments that meet their needs. This includes CE mark approval for Europe and the UK as an ED treatment for adult men without the need for a doctor's prescription and several commercial licensing deals in large markets for ED in regions such as China and South East Asia, Latin American and the Middle East.

Going forward we are continuing to conduct negotiations for licensing agreements for MED3000 in additional countries and regions and are gearing up manufacturing and supply in line with expected demand ready for first product launches, in several countries, in 2022. We have added a new FDA, EMA and UK approved contract manufacturer. Futura aims to create a global 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 across the world. We look forward to updating the market further on commercialisation in the coming months.

In a planned process, management are also working towards expanding the Company's board with appropriate business expertise and commercial acumen as Futura moves into the next phase of MED3000's commercialisation. These additions are expected to be announced shortly when the recruitment process completes.

We are also firmly focused on the US regulatory pathway for MED3000 with the US confirmatory FM71 clinical trial having recently started enrolment and running alongside the short, non-clinical study that is expected to enable US OTC designation. Everything is on track for planned MED3000 regulatory dossier submission in the USA by Q3 2022 and a potential marketing authorisation in Q1 2023. The USA remains the largest market for ED and OTC status would be a first in the USA, as it is for the majority of countries within the EU, providing patients with an accessible, new treatment option, for their ED.

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

For the six months ended 30 June 2021

	Notes	**Unaudited 6 months ended 30 June 2021**	Unaudited 6 months ended 30 June 2020	Audited year ended 31 December 2020
		£	£	£
Revenue				
Research and development costs		**(1,192,591)**	(926,802)	(1,927,658)
Administrative costs		**(709,301)**	(466,065)	(1,000,736)
Operating loss		**(1,901,892)**	(1,392,867)	(2,928,394)
Finance income		**-**	938	924
Loss before tax		**(1,901,892)**	(1,391,929)	(2,927,470)
Taxation	11	**315,000**	330,000	519,093
Total comprehensive loss for the period attributable to owners of the Parent Company		**(1,586,892)**	(1,061,929)	(2,408,377)
Basic and diluted loss per share (pence)	5	**(0.62p)**	(0.44p)	(0.99p)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2021

	Notes	**Unaudited 30 June 2021 £**	Unaudited 30 June 2020 £	Audited 31 December 2020 £
Assets				
Non-current assets				
Plant and equipment		**32,795**	51,350	42,869
Investments	6	**-**	-	-
Total non-current assets		**32,795**	51,350	42,869
Current assets				
Inventories		**-**	7,780	-
Trade and other receivables	7	**83,750**	64,871	39,790
Current tax asset		**833,805**	329,712	518,805
Cash and cash equivalents	8	**12,762,201**	2,615,085	1,018,601
Total current assets		**13,679,756**	3,017,448	1,577,196
Liabilities				
Current liabilities				
Trade and other payables	9	**(735,303)**	(950,432)	(766,525)
Total liabilities		**(735,303)**	(950,432)	(766,525)
Total net assets		**12,977,248**	2,118,366	853,540
Capital and reserves attributable to owners of the Parent Company				
Share capital	12	**574,142**	491,254	491,254
Share premium		**66,353,363**	52,814,090	52,814,090
Merger reserve		**1,152,165**	1,152,165	1,152,165
Warrant Reserve	13	**165,868**	165,868	165,868
Retained losses		**(55,268,290)**	(52,505,011)	(53,769,837)
Total equity		**12,977,248**	2,118,366	853,540

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

For the six months ended 30 June 2021

	Notes	Share Capital £	Share Premium £	Merger Reserve £	Warrant reserve £	Other reserve £	Retained Losses £	Total Equity £
At 1 January 2020 - 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
Transactions with Owners		*81,933*	*2,811,100*	-	*165,868*	-	*67,742*	*3,126,643*
At 30 June 2020 - unaudited		**491,254**	**52,814,090**	**1,152,165**	**165,868**	**-**	**(52,505,011)**	**2,118,366**
Total comprehensive loss for the period		-	-	-	-	-	(1,346,448)	(1,346,448)
Share-based payment		-	-	-	-	-	81,622	81,622
Shares issued during the period		-	-	-	-	-	-	-
Transactions with Owners		-	-	-	-	-	*81,622*	*81,622*
At 31 December 2020 - 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	12	67,888	12,053,273	-	-	-	-	12,121,161
Convertible loan notes and warrants issue	13	-	-	-	118,864	196,909	-	315,773
Shares issued on conversion of convertible loan notes and exercise of warrants	13	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 2021 - unaudited		**574,142**	**66,353,363**	**1,152,165**	**165,868**	**-**	**(55,268,290)**	**12,977,248**

CONSOLIDATED STATEMENT OF CASH FLOWS

For the six months ended 30 June 2021

	Unaudited 6 months ended 30 June 2021 £	Unaudited 6 months ended 30 June 2020 £	Audited year ended 31 December 2020 £
Cash flows from operating activities			
Loss before tax	**(1,901,892)**	(1,391,929)	(2,927,470)
Adjustments for:			
Depreciation	**11,455**	12,353	25,008
Finance income	**-**	(938)	(924)
Share-based payment charge	**88,439**	67,742	149,364
Cash flows used in operating activities before changes in working capital	**(1,801,998)**	(1,312,772)	(2,754,022)
Decrease in inventories	**-**	-	7,780
(Increase) / decrease in trade and other receivables	**(43,960)**	36,321	61,401
Decrease in trade and other payables	**(31,222)**	(3,897,088)	(4,080,996)
Cash used in operations	**(1,877,180)**	(5,173,539)	(6,765,837)
Income tax received	**-**	2,222,194	2,222,482
Net cash used in operating activities	**(1,877,180)**	(2,951,345)	(4,543,355)
Cash flows from investing activities			
Purchase of plant and equipment	**(1,381)**	(3,910)	(8,371)
Interest received	**-**	938	924
Cash used in investing activities	**(1,381)**	(2,972)	(7,447)
Cash flows from financing activities			
Issue of ordinary shares	**12,294,481**	3,270,533	3,270,534
Conversion of Convertible loan notes and warrants	**2,000,000**	-	-
Expenses paid in connection with share issues	**(672,320)**	(211,632)	(211,632)
Cash generated by financing activities	**13,622,161**	3,058,901	3,058,902
Increase/(decrease) in cash and cash equivalents	**11,743,600**	104,584	(1,491,900)
Cash and cash equivalents at beginning of period	**1,018,601**	2,510,501	2,510,501
Cash and cash equivalents at end of period	**12,762,201**	2,615,085	1,018,601

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 2021 were authorised for issue in accordance with a resolution of the Directors on 28 September 2021. 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 ended 31 December 2020, 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 2021 and for the six months ended 30 June 2020 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 2020 has been extracted from the financial statements of the statutory accounts ("Annual Report") of Futura Medical plc, which were prepared in accordance with International accounting standards in conformity with the requirements of the Companies Act 200 that were applicable for the year ended 31 December 2020 and does not constitute the full statutory accounts for that period. The Annual Report for 2020 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.

New convertible loan notes were issued and converted within this period. The group's accounting policy for convertible loan notes is detailed below.

Investments in associates

Associates are entities over which the entity has significant influence but not control or joint control.

Investments in associates are accounted for using the equity method. Under the equity method, the share of the profits or losses of the associate is recognised in profit or loss and the share of the movements in equity is recognised in other comprehensive income. Investments in associates are carried in the statement of financial position at cost plus post-acquisition changes in the consolidated entity's share of net assets of the associate. Goodwill relating to the associate is included in the carrying amount of the investment and is neither amortised nor individually tested for impairment. Dividends received or receivable from associates reduce the carrying amount of the investment.

When the Group's share of losses in an associate equals or exceeds its interest in the associate, including any unsecured long-term receivables, the Group does not recognise further losses, unless it has incurred obligations or made payments on behalf of the associate.

2. Accounting policies (continued)

Investments in associates (continued)

The Group discontinues the use of the equity method upon the loss of significant influence over the associate and recognises any retained investment at its fair value. Any difference between the associate's carrying amount, fair value of the retained investment and proceeds from disposal is recognised in profit or loss.

Convertible loan notes

The component of the convertible notes issued by the Group which exhibits the characteristics of a financial liability is recognised as a liability in the statement of financial position, net of transaction costs.

On the issue of the convertible notes the fair value of the liability component is determined using a market rate for an equivalent non-convertible bond and this amount is recorded as a non-current liability measured at amortised cost until extinguished on conversion or redemption. The increase in the liability due to the passage of time is recognised as a finance cost. The remainder of the proceeds are allocated to the conversion option that is recognised and included in shareholders equity as an other reserve, net of transaction costs. The carrying amount of the conversion option is not remeasured in the subsequent years. The corresponding interest on convertible notes is expensed to profit or loss.

Other reserve

On initial recognition of the convertible loan notes the consideration received for issuing the notes was split between the equity and liability components in accordance with IAS 32 'Financial Instruments: Presentation'. This other reserve represents the equity component of the convertible loan notes.

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.

3.1 Going concern

The Group has reported a loss after tax for the six months ended 30 June 2021 of £1.59 million (six months ended 30 June 2020: £1.06 million, year ended 31 December 2020: £2.41 million). The Group holds cash balances of £12.76 million at 30 June 2021 (30 June 2020: £2.62 million, 31 December 2020: £1.02 million).

In the six months to 30 June 2021, the Group concluded equity funding arrangements totalling £14.29 million. 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. The Directors also have a reasonable expectation that the Group will be able to generate other funding through entering into

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

3.1 Going concern (continued)

strategic collaborations for the commercialisation of MED3000 product following regulatory approval across UK and Europe in April 2021 and approval in the USA expected to follow.

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 £88,439 for the six months ended June 2021 (six months ended 30 June 2020: £67,742, year ended 31 December 2020: £149,364), the volatility method used is not expected to have a material impact on these financial statements.

Valuation of convertible loan notes

The fair value of the liability component of the convertible loan notes was calculated using the prevailing market interest rate for a similar non-convertible instrument being 10%.

Valuation of warrants

Warrant instruments were measured at fair value using the Black-Scholes model. The following inputs were used for the model:

Share price	16.5p
Warrant exercise price	22.0p
Expected life of warrant	1 year
Volatility	105.08%
Dividend yield	0%
Risk free interest rate	0.14%
Fair value	5.23p

3.3 Judgements

Conversion of convertible loan notes and warrant instruments

The Group issued a new convertible loan note and warrants on 4 March 2021. In accordance with the Group's accounting policy as detailed in note 2, the liability and equity components of the instruments were calculated at fair value as detailed in note 13. These instruments were subsequently converted to equity before the period end of 30 June 2021. Management has concluded that the £1,184,227 liability converted to equity at its liquidated sum of £1.5m resulting in an increase in retained losses of £315,773 with a corresponding increase in share premium. On conversion, the warrant reserve and

3. Critical accounting judgements, assumptions and estimates (continued)
3.3 Judgements (continued)

other reserve amounting to £315,773 created on the issue of the two instruments also reverses therefore decreasing retaining losses by the same amount.

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.

Initial accounting for investments in associated undertakings

During the year the Group entered into a collaboration agreement with Pride Century Ventures Limited ("Pride"). A special purpose vehicle ("SPV") was set up for the purpose of conducting the activities under the collaboration agreement. On the basis that the Group was entitled to voting rights on a steering committee which directs principally all of the relevant activities of the SPV management have concluded the Group has significant influence over the SPV. In line with the Group's accounting policies and the requirements of IAS 28 Investments in Associates and Joint Ventures the SPV was initially recognised at cost.

A financing agreement was entered into at the same time as the collaboration agreement with a party related to the SPV by common control. Given the fact the two arrangements were entered into at the same time, and the relationships between the parties involved, management have assessed the two contracts to determine whether they are linked.

Management have concluded that the agreements are not linked, with the principal reasoning being:

- there are no terms in the collaboration agreement which reference the finance agreement or vice-versa;
- the two agreements were negotiated separately; and
- management believe that had one of the agreements fallen through, the other could still have proceeded on the same terms provided adequate funding to support Futura's obligations under the collaboration agreement could be sourced from elsewhere.

There was no initial consideration payable in respect of entering into the collaboration agreement, and given the conclusions above, management have assessed that the initial cost of investment is £nil. This meets with management's expectations on the basis that the Chinese market accessed as part of the collaboration agreement would be difficult to access without incurring significant additional costs, and whilst the agreement allows for a future revenue stream, no approvals had been granted over the product being licenced for research under this agreement at the time it was entered into. As such, the value of any future revenue streams was uncertain at the time the contract was made.

Had management concluded that the two agreements were linked it would have been necessary to determine the fair value of each item within the agreement, an initial cost of investment would have been recognised with a corresponding adjustment to the initial recognition of the finance agreement and impacts to the subsequent accounting of the finance agreement through the interest charge.

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 £1,586,892 (six months ended 30 June 2020: loss of £1,061,929; year ended 31 December 2020: loss of £2,408,377) and on a weighted average number of shares in issue of 254,590,594 (six months ended 30 June 2020: 241,794,738; year ended 31 December 2020: 243,721,303). 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. Investments

During the year the Group entered into a collaboration agreement with Pride Century Ventures Limited ("Pride"). A special purpose vehicle ("SPV") was set up for the purpose of conducting the activities under the collaboration agreement. On the basis that the Group was entitled to voting rights on a steering committee which directs principally all of the relevant activities of the SPV management have concluded the Group has significant influence over the SPV. In line with the Group's accounting policies and the requirements of IAS 28 Investments in Associates and Joint Ventures the SPV was initially recognised at cost. Management have concluded that the initial cost of investment was £nil (see note 3.3).

7. Trade and other receivables

	Unaudited 30 June 2021 £	Unaudited 30 June 2020 £	Audited 31 December 2020 £
Amounts receivable within one year:			
Trade receivables	**21,333**	5,627	5,627
Other receivables	**10,440**	10,440	10,440
Financial assets	**31,773**	16,067	16,067
Prepayments and accrued income	**51,977**	48,804	23,723
	83,750	64,871	39,790

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.

8. Cash and cash equivalents

	Unaudited 30 June 2021 £	Unaudited 30 June 2020 £	Audited 31 December 2020 £
Cash at bank and in hand	**12,762,201**	2,241,367	644,729
Sterling fixed rate short-term deposits	**-**	373,718	373,872
	12,762,201	2,615,085	1,018,601

9. Trade and other payables

	Unaudited 30 June 2021 £	Unaudited 31 December 2020 £	Audited 31 December 2020 £
Trade payables	**483,502**	381,838	182,900
Social security and other taxes	**43,926**	56,142	64,092
Accrued expenses	**207,875**	512,452	519,533
	735,303	950,432	766,525

10. 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.

11. Taxation

The Group's tax credit in the six months ended 30 June 2021 was £0.32 million (six months ended 30 June 2020: £0.33m, year ended 31 December 2020: £0.52 million). The current period tax credit relates to anticipated R&D tax credits in respect of claims not yet submitted for the 2021 financial year.

12. Share capital

Authorised	**30 June 2021 Number**	30 June 2020 Number	31 December 2020 Number	**30 June 2021 £**	30 June 2020 £	31 December 2020 £
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 2021 Number**	30 June 2020 Number	31 December 2020 Number	**30 June 2021 £**	30 June 2020 £	31 December 2020 £
Ordinary shares of 0.2 pence each	**287,070,971**	245,626,926	245,626,926	**574,142**	491,254	491,254

12. Share capital (continued)

The number of issued ordinary shares as at 1 January 2021 was 245,626,926. During the period of six months ended 30 June 2021, the Company issued 41,444,045 ordinary shares of 0.2 pence with each ordinary share carrying the right to one vote as follows:

		£	Number
March 2021	Exercise of Share Options	30,600	425,000
April 2021	Non-Executive Director Share Award	21,581	176,318
April 2021	Exercise of Share Options	27,000	360,000
April 2021	Exercise of Share Options	75,000	250,000
April 2021	Exercise of Share Options	140,300	460,000
April 2021	Exercise of Warrants	500,000	2,272,727
April 2021	Conversion of Convertible Loan Notes	1,500,000	7,500,000
June 2021	Placing and Retail Offer	12,000,000	30,000,000
		14,294,481	**41,444,045**

13. Convertible loan notes and warrant instrument

On 4 March 2021, the Company created 100 £15,000 unsecured convertible loan notes ("Notes"). The Notes attract an interest rate of 2% per annum payable annually following an initial interest-free period of 180 days. The noteholder was entitled, at any time within 36 months of the date of the instrument ("Maturity Date"), to serve a conversion notice on the Company to convert all or some only of the outstanding Notes into fully paid ordinary shares at a conversion price of £0.20 per share. To the extent the Notes would not be converted at the Maturity Date, the outstanding principal amount of the Notes, together with any accrued interest, would have been redeemable.

In addition, 2,272,727 warrants ("Warrants") were issued to the noteholder to subscribe to ordinary shares exercisable within 48 months of issue at a conversion price of £0.22 taking the total number of warrants in issue to 13,210,227. The warrants were valued using the Black-Scholes model.

The initial value of the debt component of the Notes was calculated as £1,184,227. The cash flows attached to the Notes up to the Maturity Date were calculated and discounted at an appropriate venture debt rate of 10%. The fair value of the Warrants was calculated at £118,864 and the residual value of the equity component of the Notes was calculated as £196,909.

On 1 April 2021, the noteholder exercised the Warrants in full at an exercise price of £0.22 and was issued with 2,272,727 ordinary shares. On 15 April 2021, the noteholder converted the loan notes in full and was issued with 7,500,000 ordinary shares.

14. 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

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