

Final Results

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Destiny Pharma PLC
29 April 2020

Destiny Pharma plc
("Destiny Pharma" or "the Company")

Audited results for the year ended 31 December 2019 and clinical development update

Company funded through to Q4 2021

Patient recruitment for XF-73 Phase 2b trial temporarily paused due to COVID-19 pandemic

Brighton, United Kingdom - 29 April 2020 - Destiny Pharma ("the Company"; AIM: DEST), a clinical stage biotechnology company focused on the development of novel, hospital infection prevention treatments that address the global challenge of antimicrobial resistance (AMR), announces its audited financial results for the year ended 31 December 2019.

Financial and corporate highlights

- Strong cash position with cash and term deposits at 31 December 2019 of £7.5 million (2018: £12.1 million)
- Increase in R&D expenditure to £3.8 million (2018: £3.5 million) due to planned clinical development costs
- Cash runway extended to Q4 2021 through careful management of operational activities
- Appointment of Debra Barker, M.D. as Non-Executive Director

Operational highlights

XF-73 for prevention of post-surgical infections

- Phase 2b commenced in April 2019, with 68 patients currently recruited out of a target of 200
 - Study currently paused due to impact of COVID-19
- Publication of positive Phase 1 results from an independent study in the Journal of Global Antimicrobial Resistance (Yendewa *et al*, 2019) concluded:
 - Application of a nasal gel formulation of XF-73 in healthy volunteers was safe, well-tolerated and generated minimal side effects
 - Treatment with XF-73 was also associated with a rapid reduction in nasal *Staphylococcus aureus* in all subjects
- "Non-irritant" classification awarded to XF-73 nasal gel following positive results from a Phase 1 safety clinical study examining the drug's potential to cause irritation when administered topically
- Prototype XF-73 nasal gel pack for the final marketed product being developed to deliver an easy-to-use, single dose, nasal gel tube to enable precise delivery and reduce wastage

Earlier pipeline and research grants

- MedPharm collaboration signed to develop new XF drug formulations as treatments for dermal and ocular infections
- Good progress on research projects with Cardiff University, University of Southampton and Aston University examining XF drugs in established infection models for dermal, respiratory and biofilm related indications
- Award of fourth research grant in collaboration with Sheffield University in September 2019 examining selected XF drugs in bacterial and fungal ocular infection models

Post-period highlights

- New XF formulations developed with promising drug release profiles and scope for delivery of XF drugs designed to treat dermal and ocular infections

Impact of COVID-19

The COVID-19 pandemic has slowed recruitment in the Company's lead Phase 2b clinical trial with XF-73 for the prevention of post-surgical infections. Destiny Pharma has also seen a slowdown in some of its grant funded research projects as staff and facilities follow government guidance although the business impact here is minimal. Destiny Pharma is complying with international governmental advice and requirements across its operations to prioritise safety with all employees able to continue working effectively from home with minimal disruption to day-to-day operations as a result of the Company's existing virtual model. Through careful management of cash resources Destiny Pharma is currently able to manage the impact of the pandemic and is closely monitoring the situation.

Neil Clark, Chief Executive Officer of Destiny Pharma, commented:

"We made good progress in 2019 and were very pleased to start recruitment into our lead Phase 2b programme evaluating the potential of our lead product, XF-73, to prevent post-surgical infections. Unfortunately, the study is now effectively paused due to restrictions on performing non-COVID-19 related clinical trials during the pandemic. We are working hard to accelerate recruitment when these restrictions are lifted and look forward to completing this important Phase 2b study as soon as possible. The Company remains well-funded and through careful management of our cash resources we have funding through to Q4 2021.

"It has been widely reported that the treatment of many patients infected with COVID-19 has been significantly complicated by secondary bacterial infections that take hold and contribute to the mortality rate. This highlights yet again the need for new, safe and effective antimicrobial drugs. We continue to believe that our proprietary XF-platform is well-positioned to generate such products and remain very positive about the future of Destiny Pharma."

This announcement has been released by Neil Clark, CEO, on behalf of the Company

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About Destiny Pharma

Destiny Pharma is an established, clinical stage, innovative biotechnology company focused on the development of novel, cost effective medicines that represent a new approach to the treatment of infectious disease. These potential new medicines are being developed to address the need for new drugs for the prevention and treatment of life-threatening infections caused by antibiotic-resistant bacteria, often referred to as "superbugs". Tackling anti-microbial resistance has become a global imperative recognised by the World Health Organisation (WHO) and the United Nations, as well as the G7 and the G20 countries. For further information, please visit <https://www.destinypharma.com>

Forward looking statements

Certain information contained in this announcement, including any information as to the Group's strategy, plans or future financial or operating performance, constitutes "forward-looking statements". These forward looking statements may be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "projects", "expects", "intends", "aims", "plans", "predicts", "may", "will", "seeks" "could" "targets" "assumes" "positioned" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this announcement and include statements regarding the intentions, beliefs or current expectations of the Directors concerning, among other things, the Group's results of operations, financial condition, prospects, growth, strategies and the industries in which the Group operates. The directors of the company believe that the expectations reflected in these statements are reasonable, but may be affected by a number of variables which could cause actual results or trends to differ materially. Each forward-looking statement speaks only as of the date of the particular statement. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future or are beyond the Group's control. Forward looking statements are not guarantees of future performance. Even if the Group's actual results of operations, financial condition and the development of the industries in which the Group operates are consistent with the forward-looking statements contained in this document, those results or developments may not be indicative of results or developments in subsequent periods.

Chief Executive Officer's Statement

Operational review

Destiny Pharma is focused on the development of novel medicines for the treatment of infectious disease. These potential new medicines are being developed to address the need for new drugs for the prevention and treatment of life-threatening infections caused by anti-microbial resistance (AMR). AMR poses a serious threat to public health and is listed as a major healthcare concern to the World Health Organization (WHO). Lord O'Neill's Independent Review on AMR, published in May 2016, predicts ten million deaths and an estimated \$100 trillion cost by 2050. The UK government's update on their 5- and 20-year AMR plans, announced in 2019 and 2020, respectively, also confirmed the importance of addressing AMR and innovation in the development of novel anti-infectives. More recently, the current COVID-19 pandemic highlights the urgent need for new anti-infective treatments and it is being reported that almost half of COVID-19 related deaths are associated with bacterial, as well as the viral infection (Zhou et al, 2020).

The Company's lead asset, XF-73 (exeporfinium chloride), has been developed from Destiny Pharma's novel, antimicrobial XF drug platform. Unlike most antibiotics, XF drugs have not been seen to generate bacterial resistance in industry-standard microbiology tests and therefore have significant potential to address the global threat of AMR. This has been recognised by the FDA's award of QIDP (Qualifying Infectious Disease Product) status to XF-73 has been shown to kill bacteria very rapidly and therefore may be an

effective new treatment in the reduction of bacterial infections in hospital patients including those caused by methicillin resistant *Staphylococcus aureus* (MRSA). This claim was supported by positive results from an independent Phase 1 clinical study in 60 healthy US volunteers using a nasal gel formulation of XF-73. The results were published in the peer reviewed Journal of Global Antimicrobial Resistance in October 2019 (Yendewa et al, 2019). The Phase 1 study was conducted and sponsored by the National Institute of Allergy and Infectious Diseases as part of the US National Institutes of Health (NIH). In addition to the study reporting a favourable safety and local tolerability profile of the nasal gel formulation (the primary objective), the study also noted, as expected, that exposure to XF-73 produced a rapid reduction in levels of nasal *Staphylococcus aureus* in all subjects. The Company is aiming to replicate these results in the current Phase 2b study with XF-73.

XF-73 is administered topically as a nasal gel whereby it reduces the nasal carriage of the bacteria *Staphylococcus aureus* which is the source of many post-surgical bacterial infections. Approximately a third of all patients across the world have this nasal carriage as they enter surgery and it has the potential to be a very valuable market due to the millions of surgical procedures carried out each year.

The Company believes XF-73 is clearly differentiated from traditional antibiotics and many current anti-infective drugs in development due to the XF approach being prophylactic, following the well-established medical truth that "prevention is better than cure". The XF's target product profile also addresses the key issue of AMR. This belief is supported by feedback from our market research targeting physicians, pharmacists and payers in the US who are responsible for managing hospital infections and the associated cost implications. This research also supports our proposed pricing strategies for XF-73 nasal gel as a new hospital product and the company estimates that there is a \$1 billion peak sales opportunity in US alone.

XF-73 nasal gel - Phase 2b clinical trial initiated in 2019 is temporarily paused due to impact of COVID-19 pandemic

The Phase 2b study design was finalised in Q1 2019 and started recruiting patients in the US and Europe during Q2 2019. The European sites were set up on schedule but the rate of recruitment in the US sites was slower than expected in the second half of 2019. In response, the Company acted to bring in further sites in an additional European country to improve recruitment rates. However, due to the unprecedented impact of the COVID-19 pandemic, including government measures to contain the spread of the disease and increased pressure on hospital facilities across the globe, recruitment for the Company's Phase 2b clinical trial with XF-73 for the prevention of post-surgical infections has effectively been paused due to a slow-down in activity at the participating hospitals. The study has enrolled 68 patients to date. The Company will resume the trial as soon as possible and will provide further guidance regarding the revised timing of completion of the study in due course. Patients already treated in the study will receive follow-up consultations on a remote basis to ensure patient safety. The quality of the Phase 2b clinical trial has not been compromised by this delay.

The Company still plans to report an interim analysis of the XF-73 Phase 2b clinical trial as soon as the required number of patients has been recruited and the data analysed. This will be conducted by an Independent Safety Monitoring Board but is now unlikely to be in Q2 2020 as previously expected due to the delays caused by COVID-19.

The trial is a multi-centre, randomised, blinded, placebo-controlled study of multiple applications of a single concentration of XF-73 nasal gel to assess the microbiological effect of XF-73 on commensal *Staphylococcal aureus* nasal carriage in patients scheduled for cardiac surgical procedures deemed to be at high risk of post-operative *Staphylococcal aureus* infection.

A second Phase 1 dermal safety study, looking at potential skin irritation of XF-73 nasal gel formulation, was completed successfully in 2019. This study reported XF-73 as having a very benign profile with low cumulative irritancy scores compared to the water control and gives XF-73 a "non-irritant" classification as a topical/dermal development candidate. This excellent dermal safety data was also beneficial in clarifying the pathway for our new dermal infection programme.

In parallel with the clinical work, good progress has been made with improving the efficiency of the synthesis and scale up of XF-73 in order to further improve the costs of goods. Work is also progressing well on a prototype final product presentation with the objective of offering an accurate, stable, easy-to-use single dose final formulation.

XF-73 dermal - targeting the multi-billion-dollar dermal infection market

The Company is also developing XF-73 as a new treatment for diabetic foot ulcer infections (DFUs). Driven by the growing number of diabetics and their associated ulcer infections this represents a significant market opportunity for XF-73. As with all anti-infectives AMR is also a concern within this market. There is no dominant treatment for DFUs, and specialist physicians are very interested in working to find better treatment options including new topical formulations. The target product profile of XF-73 also tested favourably with dermal clinicians looking for better treatments for the smaller market for burns/wound infections. The Phase 1 skin irritation studies completed in the period were the first data supporting the use of XF-73 on damaged skin and as stated above the "non-irritant" profile is very promising.

Destiny Pharma completed work during 2019 with Medpharm, a world leading contract provider of topical and transdermal product design and formulation development services.. The collaboration has now developed new prototype formulations of XF-73 for infections in DFUs and burns wounds which is estimated to be a \$0.5 billion global opportunity for the Company based on the incidence of such infections, the costs of the associated medical care and a realistic product pricing of XF-73 in this new market. The next step in this project is to complete key dermal toxicology studies to deliver a package that is ready to enter the first human clinical studies.

Research collaborations

Work on earlier programmes such as respiratory, dermal, ocular, biofilms and other indications is being undertaken though grant funded research projects. There are now four of these projects underway supported by approximately £2m of grant funding and the Company is targeting new opportunities, including those that are associated with the COVID-19 pandemic.

Destiny Pharma has a research collaboration agreement with Aston University to examine novel compounds from the XF-platform and assess their potential to prevent, control and eradicate dangerous bacteria in biofilms. Serious infections are frequently caused and exacerbated by biofilms where bacteria can hide and be protected from traditional anti-infective agents. XF compounds have already shown efficacy in biofilm models and this research project will explore the potential further, including looking at the mechanisms-of-action.

A second collaboration is with the University of Southampton examining the use of the Company's novel XF compounds to prevent, control and eradicate chronic clinical infections with underlying biofilm involvement, such as those in diabetic foot ulcers and cystic fibrosis. The National Biofilms Innovation Centre (NBIC) funded collaboration plans to expand on this data using laboratory and clinical microbial biofilm models and the expertise of the team at the University of Southampton's Faculty of Environmental and Life Sciences, who have established *ex vivo* biofilm model systems and access to clinical infection samples that will be utilised in the collaboration.

A third grant was awarded in early 2019, with funding of up to £1.6 million from a collaboration established under the UK-China AMR grant fund set up by Innovate UK and the Department of Health and Social Care with the Chinese Ministry of Science and Technology. The project will examine the use of the Company's novel XF drugs (XF-73, XF-70 and DPD-207) to prevent, control, and eradicate life threatening bacteria or "superbugs" without generating resistance especially in the treatment of dermal and ocular infections. The research work will be carried out by Destiny Pharma's team in collaboration with expert groups at Cardiff University's School of Dentistry and College of Biomedical and Life Sciences, led by Professor David Williams, and a team at Tianjin Medical University, China.

The fourth grant funded project was signed in 2019 with the Sheffield Centre for Antimicrobial Resistance and Biofilms at the University of Sheffield. The project aims to establish the potential of two of the Company's proprietary XF drug compounds, DPD-207 and XF-73, as novel treatments for drug-resistant, bacterial and fungal infections in a dynamic *ex vivo* eye model. Drug resistant bacteria and fungi pose a significant threat across a range of ophthalmic infections and can result in vision impairment and blindness. Many chronic eye infections, such as bacterial keratitis and lacrimal/periorbital infections, are caused by microbes aggregating to form a biofilm. These biofilms are difficult to treat with conventional antibiotics, a problem which is exacerbated by the rise of AMR. Destiny Pharma's XF drugs have already demonstrated efficacy in killing bacteria located in biofilms in early clinical studies. The global ophthalmic drugs market size is currently valued at approximately \$30 billion. A significant proportion of this market is therapeutics for ocular infections which the Company estimates to be worth over \$1 billion.

All four of these grant funded projects are up and running and we are looking forward to their progress and the potential to identify new product opportunities for the XF platform.

In addition, it is emerging that secondary bacterial respiratory infections take advantage of immune-compromised COVID-19 intensive care patients and are a significant cause of mortality in this pandemic (Zhou et al, 2020). The Company believes XF-73 has the potential to be part of new treatment regimens that could help reduce the incidence of such bacterial infections by reducing the bacterial carriage quickly in COVID-19 infected patients in the ICU. As part of this process, Destiny Pharma is actively exploring government funded initiatives that could test the utility of XF-73 as a new COVID-19 related treatment and will update on progress in due course.

Globally recognised issue that urgently needs addressing

International reviews and initiatives continued to take place in support of tackling the global issue of antibiotic resistance. These have included discussions and announcements at G7, G20 and United Nations meetings, as well as the WHO's GARDP and DRIVE-AB, an EU/industry partnership. Mechanisms to support the clinical development of new anti-infectives proposed include additional "push" grant incentives, as well as significant "pull" market entry rewards. Both the UK and US governments have announced new initiatives that aim to deliver clear financial support for novel anti-infectives, and other countries are monitoring their impact and success. These efforts will only increase as a result of the COVID-19 pandemic. Destiny Pharma will continue to contribute to policy development and will apply for appropriate grants and other non-dilutive funding where they fit with the Company's research and development plans.

Outlook

Despite the temporary recruitment delays due to COVID-19, Destiny Pharma is funded to develop its lead asset, XF-73, through its Phase 2b clinical programme. The aim is to deliver a robust package for partnering and/or further development into Phase 3. Importantly, market analysis continues to support the clinical need and commercial opportunity for XF-73 in the prevention of post-surgery hospital infections, such as MRSA, which is estimated to be over a \$1 billion market opportunity in the US alone.

The Company's funds, augmented by four grant awards, are also being used to develop new clinical candidates from the Company's pre-clinical pipeline and we continue to look at new programmes, including those related to the COVID-19 outbreak. The Board is confident that the Company is funded to execute on its business strategy and to progress its lead and follow-on programmes through its planned studies in 2020. There is continuing international support for the development of novel anti-infective drugs, which is being increased following the issues raised by the current pandemic where there is an unmet medical need for effective treatments of secondary bacterial infections. Destiny Pharma's unique platform is very well-positioned to meet this global need and the Company will continue to develop its pipeline.

Neil Clark
Chief Executive Officer
29 April 2020

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Chief Financial Officer's Statement

Financial review

We increased activity across our scientific and clinical programmes during 2019, particularly during the second half of the year. Our key focus was on progressing our lead programme through a Phase 2b clinical trial which commenced during the year and which accounts for the majority of our R&D spend. We also continued to develop our earlier programmes in conjunction with our research partners and were pleased to announce our fourth collaboration, with Sheffield University, during the year.

Revenue

Destiny Pharma is a clinical stage research and development company and is yet to commercialise and generate sales from its current programmes. The Company received grant income of £0.3 million during the period.

Administrative expenses

Administrative expenses, which excludes the share-based payment charge of £0.2 million (2018: £0.7 million), during the period amounted to £5.7 million (2018: £5.3 million). Included within this total are R&D costs totalling £3.8 million (2018: £3.5 million) which reflect the increase in activity with regard to our scientific and clinical programmes, in particular our Phase 2b clinical trial during the period.

Other administrative costs marginally increased from £1.8 million to £1.9 million due to an increase in foreign exchange losses during the period which were partly offset by a reduction in other operating costs.

Taxation

The Company's research and development (R&D) activities are eligible for the UK R&D small or medium-sized enterprise ("R&D tax credit") scheme, which provides additional taxation relief for qualifying expenditure on R&D activities, with an option to surrender a portion of tax losses arising from qualifying activities in return for a cash payment from HM Revenue & Customs ("HMRC"). The company received a repayment of £0.8 million in respect of the R&D tax credit claimed in respect of the year ended 31 December 2018, and the R&D tax credit receivable in the balance sheet of £0.8 million is an estimate of the cash repayment the Company expects to qualify for in respect of activities during the year ended 31 December 2019. However, as at the date of this report, these amounts have not yet been agreed with HMRC.

Loss per share

Basic and diluted loss per share for the year was 10.7 pence (2018: 11.9 pence).

Cash, cash equivalents and term deposits

The Company's cash, cash equivalents and term deposits at the year-end totalled £7.5 million (2018: £12.1 million).

The net cash outflow from operating activities in 2019 was £4.6 million against an operating loss of £5.5 million, with the major reconciling items being the non-cash charge for share-based payments of £0.2 million, the R&D credit received of £0.8 million and other net movements in working capital of £(0.1) million.

Outlook

The Board believes the company remains well funded to execute on its business strategy and to progress its lead and follow-on programmes in 2020 and 2021.

Shaun Claydon
Chief Financial Officer
29 April 2020

Statement of comprehensive income

For the year ended 31 December 2019

	Notes	Year ended 31 December 2019 £	Year ended 31 December 2018 £
Continuing operations			
Other operating income	4	305,906	-
Administrative expenses		(5,687,003)	(5,346,170)
Share-based payment expense		(203,655)	(737,687)
Loss from operations		(5,584,752)	(6,083,857)
Finance income	5	63,478	75,999
Loss before tax		(5,521,274)	(6,007,858)
Taxation	6	813,250	841,144
Loss and total comprehensive loss for the year from continuing operations		(4,708,024)	(5,166,714)
Loss per share - pence			
Basic	7	(10.7)p	(11.9)p
Diluted	7	(10.7)p	(11.9)p

Statement of financial position

As at 31 December 2019

	Notes	As at 31 December 2019 £	As at 31 December 2018 £
Assets			
Non-current assets			
Property, plant and equipment		32,922	30,421
Non-current assets		32,922	30,421

Current assets			
Trade and other receivables	8	911,198	930,759
Cash and cash equivalents	9	7,479,642	7,060,821
Other financial assets	10	-	5,000,000
Prepayments		133,702	36,406
Current assets		8,524,542	13,027,986
Total assets		8,557,464	13,058,407
Equity and liabilities			
Equity			
Share capital	11	438,652	435,626
Share premium		17,296,337	17,292,284
Accumulated losses		(9,975,664)	(5,471,295)
Shareholders' equity		7,759,325	12,256,615
Current liabilities			
Trade and other payables	12	798,139	801,792
Current liabilities		798,139	801,792
Total equity and liabilities		8,557,464	13,058,407

Statement of changes in equity

For the year ended 31 December 2019

	Share capital £	Share premium £	Accumulated losses £	Total £
1 January 2018	435,626	17,292,284	(1,042,268)	16,685,642
Comprehensive loss for the year				
Total comprehensive loss	-	-	(5,166,714)	(5,166,714)
Total comprehensive loss for the year	-	-	(5,166,714)	(5,166,714)
Contributions by and distributions to owners				
Share-based payment expense	-	-	737,687	737,687
Total contributions by and distributions to owners	-	-	737,687	737,687
31 December 2018	435,626	17,292,284	(5,471,295)	12,256,615
Comprehensive loss for the year				
Total comprehensive loss	-	-	(4,708,024)	(4,708,024)
Total comprehensive loss for the year	-	-	(4,708,024)	(4,708,024)
Contributions by and distributions to owners				
Issue of share capital	3,026	4,053	-	7,079
Share-based payment expense	-	-	203,655	203,655
Total contributions by and distributions to owners	3,026	4,053	203,655	210,734
31 December 2019	438,652	17,296,337	(9,975,664)	7,759,325

Statement of cash flows

For the year ended 31 December 2019

	Year ended 31 December 2019 £	Year ended 31 December 2018 £
Cash flows from operating activities		
Loss before income tax	(5,521,274)	(6,007,858)
Depreciation of property, plant and equipment	18,440	9,663
Share-based payment expense	203,655	737,687
Finance income	(63,478)	(75,999)
	(5,362,657)	(5,336,507)
Increase in trade and other receivables and prepayments	(79,800)	(23,162)
Decrease in trade and other payables	(3,653)	404,317
Cash used in operations	(5,446,110)	381,155
Tax received	815,316	233,908
Net cash used in operating activities	(4,630,794)	(4,721,444)
Cash flows from investing activities		
Purchase of property, plant and equipment	(20,942)	(17,771)
Sale of other financial assets	5,000,000	-
Interest received	63,478	75,999
Net cash inflow from investing activities	5,042,536	58,228
Cash flows from financing activities		
New shares issued	7,079	-
Net cash inflow from financing activities	7,079	-
Net increase/(decrease) in cash and cash equivalents	418,821	(4,663,216)
-Cash and cash equivalents at the beginning of the year	7,060,821	11,724,037
Cash and cash equivalents at the end of the year	7,479,642	7,060,821

Notes to the financial statements

1. Corporate information

Destiny Pharma plc (the "company") was incorporated and domiciled in the UK on 4 March 1996 with registration number 03167025. The company's registered office is located at Unit 36, Sussex Innovation Centre, Science Park Square, Falmer, Brighton BN1 9SB.

The company is engaged in the discovery, development and commercialisation of new antimicrobials that have unique properties to improve outcomes for patients and the delivery of medical care into the future.

2. Basis of preparation

The financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the European Union. The financial statements have been prepared under the historical cost convention.

The company's financial statements have been presented in pounds sterling ("GBP"), being the functional and presentation currency of the company.

Going concern

The company has not yet recorded any revenues and funds its operations through periodic capital issues and research grants. Management prepares detailed working capital forecasts which are reviewed by the Board on a regular basis. Cash flow forecasts and projections take into account sensitivities on receipts, and costs. In their assessment of going concern the directors have considered the possible impact on the business of the COVID-19 pandemic. This has to date had no significant impact on the company's operations other than an anticipated short-term delay to the existing Phase 2b clinical study's timetable. Having made relevant and appropriate enquiries, including consideration of the company's current cash resources and the working capital forecasts, the Directors have a reasonable expectation that the company will have adequate cash resources to continue to meet the requirements of the business for at least the next twelve months. Accordingly, the Board continues to adopt the going concern basis in preparing the financial statements.

Standards and interpretations issued

a) New Standards, interpretations and amendments effective from 1 January 2019

IFRS16 'Leases' became applicable to the Company on 1 January 2019. The Company has elected not to apply the requirements of paragraphs 22 to 49 of IFRS16 in relation to short term leases and has no material leases which are other than short term. The adoption of IFRS16 therefore had no impact on the financial statements and no adjustments were required as a consequence of its adoption.

b) New Standards, interpretations and amendments not yet effective

At the date of authorisation of the company's financial statements, certain new standards, amendments and interpretations to existing standards have been published by the International Accounting Standards Board but are not yet effective and have not been adopted early by the company. The most significant of these are as follows, which are both effective for the period beginning 1 January 2020:

- IAS 1 *Presentation of Financial Statements* and IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors* (Amendment - Definition of Material)
- Revised Conceptual Framework for Financial Reporting

All relevant standards, amendments and interpretations to existing standards will be adopted in the company's accounting policies in the first period beginning on or after the effective date of the relevant pronouncement.

The Directors do not anticipate that the adoption of these standards, amendments and interpretations will have a material impact on the company's financial statements in the periods of initial application

3. Segment reporting

The chief operating decision-maker is considered to be the Board of Directors of the company. The chief operating decision-maker allocates resources and assesses performance of the business and other activities at the operating segment level.

The chief operating decision-maker has determined that the company has one operating segment, the development and commercialisation of pharmaceutical formulations. All activities take place in the United Kingdom.

4. Other operating income

	31 December 2019 £	31 December 2018 £
Government grants received during the year	269,216	-
Government grants accrued for at 31 December	36,690	-
	305,906	-
Included in trade and other receivables (note 8)	36,690	-

Grant funding has been received to support research and development activities which seek to extend the knowledge base and activity profile of the Company's novel XF drugs. There are no unfulfilled conditions or contingencies attached to these grants.

5. Net finance income

	31 December 2019 £	31 December 2018 £
Finance income		

Deposit account interest	63,478	75,999
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6. Income tax

	31 December 2019 £	31 December 2018 £
Research and development tax credits based on costs in the financial year	(839,079)	(841,144)
Non recoverable tax credit in prior year	25,829	-
	(813,250)	(841,144)

Tax reconciliation

	31 December 2019 £	31 December 2018 £
Loss before tax	(5,521,274)	(6,007,858)
Loss before tax multiplied by the UK corporation tax rate of 19% (2018: 19%)	(1,049,042)	(1,141,493)
Effects of:		
Non-deductible expenditure	38,911	148,637
Employee share acquisition relief	(43,860)	-
R&D enhanced expenditure	(621,447)	(622,976)
Lower tax rate on R&D losses	260,404	261,044
Tax losses carried forward	575,955	513,644
Total tax credit on loss	(839,079)	(841,144)

There were no tax charges in the period. There are tax losses available to carry forward amounting to approximately £16.8 million (2018: £13.7 million), which includes £0.2 million (2018: £0.7 million) in respect of tax deductions on share options. A deferred tax asset on losses is not recognised in the accounts due to the uncertainty of future profits against which they will be utilised.

7. Loss per ordinary share

The calculation for loss per ordinary share (basic and diluted) for the relevant period is based on the earnings after income tax attributable to equity shareholders for the period. As the company made losses during the period, there are no dilutive potential ordinary shares in issue, and therefore basic and diluted loss per share are identical. The calculation is as follows:

	31 December 2019 £	31 December 2018 £
Loss for the year attributable to shareholders	(4,708,024)	(5,166,714)
Weighted average number of shares	43,799,945	43,562,598
Loss per share - pence		
- Basic and diluted	(10.7)p	(11.9)p

8. Trade and other receivables

	31 December 2019 £	31 December 2018 £
Other receivables	72,119	89,615
Research and development tax repayment	839,079	841,144
	911,198	930,759

9. Cash and cash equivalents

	31 December 2019 £	31 December 2018 £
Cash and bank balances	7,479,642	7,060,821

10. Other financial assets

	31 December 2019 £	31 December 2018 £
Term deposits with maturities greater than three months	-	5,000,000

11. Share capital

	31 December 2019 Number	31 December 2018 Number
Ordinary shares of £0.01 each		
Authorised⁽¹⁾	n/a	n/a
Allotted and fully paid		
At 1 January	43,562,598	43,562,598
Issued for cash during the year	302,597	-
At 31 December	43,865,195	43,562,598

(1) During the year ended 31 December 2017 the company adopted new Articles of Association, which do not require the company to have authorised share capital.

	31 December 2019	31 December 2018
	£	£
Authorised Allotted and fully paid	n/a 438,652	n/a 435,626
	31 December 2019	31 December 2018
	£	£
Share premium account	17,296,337	17,292,284

Each ordinary share ranks pari passu for voting rights, dividends and distributions and return of capital on winding up.

Share options

The expense arising from share-based payment transactions recognised in the year ended 31 December 2019 was £203,655 (year ended 31 December 2018: £737,687).

The company's share-based payment arrangements are summarised below.

Share option schemes

As part of its strategy for executive and key employee remuneration, the company issued share options under two schemes established on 15 November 2000 - an Unapproved Scheme and an EMI Scheme (the "Old Schemes"). During 2017, the company established two new share option schemes - the LTIP Employee Scheme and the LTIP Non-Employee Scheme, both of which were established on 18 April 2017 (the "New Schemes"). Awards under the LTIP Employee Scheme are made to qualifying employees and in accordance with Schedule 5 of the Income Tax (Earnings and Pensions) Act 2003 so that, provided awards are within the qualifying limits, the awards qualify as EMI options. Any awards under the LTIP Employee Scheme which do not fall within the qualifying limits do not qualify as EMI options. Awards under the LTIP Non-Employee Scheme do not qualify as EMI options.

The principal terms of the company's share option schemes are as follows:

Unapproved Scheme

Options are granted at the discretion of the Directors. The price per share to be paid on exercise of an option will be the market value as agreed with the Share Valuation Division of HM Revenue & Customs at the time of the grant of the option and as detailed in the option certificate. Options may be exercised three years from the date of grant and lapse on the expiry of ten years from the date of grant of the option.

EMI Scheme

Options granted under the EMI Scheme are on substantially the same terms as options granted under the Unapproved Scheme, save that the EMI Scheme rules comply with the terms of the enterprise management incentive as set out in Schedule 14 of the Finance Act 2000.

Employee LTIP Scheme

Options are granted at the discretion of the Directors to eligible employees in accordance with Schedule 5 of the Income Tax (Earnings and Pensions) Act 2003 up to the limits set out therein. The price per share to be paid on exercise of an Employee LTIP Option will be the market value as agreed with HMRC at the time of the grant of the option. Options lapse on the expiry of ten years from the date of grant, the date specified in any leaver provisions or any other lapse date specified in the relevant option agreement.

Non-Employee LTIP Scheme

Options are granted on substantially similar terms to the Employee LTIP Scheme except that the EMI and/or employment related provisions and requirements do not apply. These options can be granted to any Director of, or individual providing consultancy or other services to, the company.

	31 December 2019		31 December 2018	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Balance outstanding at beginning of the year	7,098,823	£0.075	6,748,823	£0.062
Granted during year	335,000	£0.010	350,000	£0.334
Exercised during year	(302,597)	£0.023	-	-
Lapsed during year	(41,000)	£1.066	-	-
Options outstanding at end of the year	7,090,226	£0.068	7,098,823	£0.075
Options exercisable at the end of the year	6,455,226	£0.068	6,585,823	£0.035

Modification of existing share option schemes

During May and June 2017, modifications were made to the Old Schemes by issuing replacement options in the New Schemes to participants in the Old Schemes and new awards were subsequently made to individuals under the New Schemes.

Options over 741,000 shares granted under the Old EMI Scheme and over 103,000 shares granted under the Old Unapproved Scheme were unchanged. The remaining options over 7,004,000 shares issued under the Old Schemes were modified so that, to exercise, the holders of such options now have the right to subscribe instead for an aggregate of 5,235,518 shares in the company. The number of such options and the exercise price of such options were determined by reference to the closing fair value of the ordinary shares on the day of modification. The modification of these options as described had a neutral effect on the option holders immediately before and after the amendment of the options.

After adjusting for the bonus issue on 23 January 2017, 7,848,000 share options had been issued prior to the modification at

adjusted weighted average exercise prices of between £0.2484 and £1.4522.

The estimated fair value of all share options at the modification date was calculated by applying a Black-Scholes option pricing model. In the absence of a liquid market for the share capital of the company, the expected volatility of its share price is difficult to calculate. Therefore, the Directors considered the expected volatility used by listed entities in similar operating environments to calculate the expected volatility. The resulting incremental fair value was £nil.

Grants of options

On 4 June 2019, 135,000 Employee LTIP Options were granted to certain senior employees at an exercise price of £0.01 per ordinary share and 200,000 Employee LTIP Options were granted to Neil Clark at an exercise price of £0.01 per ordinary share. These options are exercisable on or after the third anniversary of the date of grant.

The estimated fair value of share options granted during the period has been calculated by applying a Black-Scholes option pricing model. In the absence of a liquid market for the share capital of the company, the expected volatility of its share price is difficult to calculate. Therefore, the Directors have considered the expected volatility used by listed entities in similar operating environments to calculate the expected volatility. The weighted average fair value of options granted in the period was £0.78 (2018: £0.68).

The model inputs were:

	2019	2018
Share price	£0.785	£0.765/£1.115
Exercise price	£0.01	£0.01/£0.765
Expected volatility	49%	49%
Expected option life	10 years	10 years
Risk free rate	0.92%	1.5%/1.55%
Expected dividends	£nil	£nil

12. Trade and other payables

	31 December 2019 £	31 December 2018 £
Trade payables	513,508	403,552
Social security and other taxes	45,761	50,874
Accrued expenses	234,729	344,275
Pension contributions payable	4,141	3,091
	798,139	801,792

13. Statutory accounts

The financial information set out above does not constitute the company's statutory accounts for the years ended 31 December 2019 or 2018 but is derived from those accounts. Statutory accounts for 2018 have been delivered to the registrar of companies, and those for 2019 will be delivered in due course. The auditor has reported on those accounts; their reports (i) were unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006.

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