

Interim Results for 6 months ended 30 June 2019

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

Interim results for the six months ended 30 June 2019

XF-73 nasal gel Phase 2b patient recruitment underway in US and Europe, results expected mid-2020

Grant funded XF Drug research projects making good progress underlining broad potential of XF platform

Company well-funded into 2021

Brighton, United Kingdom - 23 September 2019 - Destiny Pharma (AIM: DEST), a clinical stage biotechnology company focused on the development of novel anti-microbial drugs that address clear commercial opportunities and also address the global problem of anti-microbial resistance (AMR), announces its unaudited financial results for the half-year ended 30 June 2019 and an update for the year to date.

Financial highlights

- Strong cash position with cash and term deposits at 30 June 2019 of £9.1 million (30 June 2018: £15.1 million; 31 December 2018: £12.1 million)
- Expenditure on R&D in the period of £1.7 million (half-year 2018: £1.3 million; full year 2018: £3.5 million) reflecting the increased investment in clinical programmes as described below
- Company funded through to 2021

Operational highlights

Phase 2b clinical trial: XF-73 nasal gel for prevention of post-surgical infections

- XF-73 (exeporfinium chloride) nasal gel Phase 2b trial has started enrolling 200 surgical patients in sites in the US and Europe
- European site set-up on schedule but US sites slower than expected. Consequently, recruitment expected to complete in early 2020 with results announced later in mid-2020 (previously recruitment was planned to end in Q4 2019)
- Interim safety, efficacy and futility analysis of Phase 2b trial, performed by independent safety monitoring board, planned for end of 2019
- Prototype XF-73 nasal gel pack for the final marketed product is being developed to deliver an easy-to-use, single dose, nasal gel tube to enable precise delivery and reduce wastage
- "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. This classification supports lead nasal programme and use in Phase 1 dermal infection project

Earlier pipeline and research projects

- MedPharm collaboration signed to develop new XF drug formulations as treatments for dermal and ocular infections
- Award of UK China AMR grant of up to £1.6 million to examine XF drugs potential against dermal and ocular infections
- Research projects with Cardiff, Southampton and Aston Universities making good progress examining XF Drugs in established infection models for dermal, respiratory, ocular and biofilm related indications

Governmental initiatives supporting development and commercialisation of novel anti-infectives

- UK government announced new 5 and 20 year plans to address anti-microbial resistance (AMR) including support for novel drug development and financial incentives for companies bringing such drugs to market.
- The NHS is testing the world's first 'subscription' style payment model to incentivise pharmaceutical companies to develop new drugs for resistant infections
- US government announced a healthcare reform for novel antibacterial drug payments, including an alternative pathway for new technology add-on payments (NTAPs), which increases the value of these payments to 75% for Qualified Infectious Disease Products (QIDPs): XF-73 has QIDP status.

Post-period highlights

- Award of fourth research grant in collaboration with Sheffield University examining selected XF drugs in bacterial and fungal ocular infection models

Neil Clark, CEO of Destiny Pharma, commented:

"Destiny Pharma has made good progress in the first half of the year and we are very pleased to have started recruitment of patients into the important Phase 2b study of our lead drug candidate, XF-73, for the prevention of post-surgical hospital infections. This is a major milestone for the Company and we look forward to reporting results in mid-2020 with patient recruitment planned to complete in Q1 2020.

*We remain very positive on the clinical need and commercial opportunity for XF-73 in the hospital setting which we estimate in the US alone to be peak annual product sales of \$1 billion. Our discussions with potential US hospital clinical trial sites and new, independent US studies confirm the increase in the decolonisation of nasal carriers of *Staphylococcus aureus* in the US as "best practice" ahead of major surgeries.*

Whilst our focus remains on our lead indication, we are also progressing our earlier pipeline to realise further value from the XF drug platform and we look forward to producing new data from these programmes in the next 12 months. Our successes in securing grant funding also helps offset net cash outflows and the Company is funded into 2021.

We continue to believe that Destiny Pharma's novel XF platform has the potential to deliver new anti-microbial drugs for clearly defined commercial opportunities that tackle serious infections. These are increasingly caused by superbugs and our platform has significant potential in the fight against the global rise of anti-microbial resistance."

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About Destiny Pharma

Destiny Pharma is an established, clinical stage, innovative biotechnology company focused on the development and commercialisation of novel medicines from its XF Platform that represent a new approach to the treatment of infectious disease. The company's lead programme is undergoing a Phase 2b clinical trial and is targeting the prevention of post-surgical hospital infections including MRSA. The XF drug candidates are being developed 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 - prevention is better than cure

The Company's lead asset, XF-73, 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 to date and therefore have significant potential to address the global threat of AMR. 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). 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.

This strong market need is supported by feedback from 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 the proposed pricing strategies for XF-73 nasal gel as a new hospital product.

XF-73 nasal gel - Phase 2b clinical trial started and recruiting 200 patients undergoing cardiac surgery

The Phase 2b study design was finalised and has now started recruiting patients in the US and Europe. The European site was set up on schedule but the pace of recruitment over the summer months has been slower than expected in the US sites and therefore recruitment is now expected to complete in Q1 2020, which is three months later than previously anticipated. An interim safety, efficacy and futility analysis, to be conducted by an Independent Safety Monitoring Board, is planned for the end of 2019.

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. The study is larger than originally planned and reflects the expert advice taken on statistical parameters, microbiological end-points and delivering the most complete study possible. The larger study also has the advantage of exposing even more sites and patients in the hospital setting to the XF-73 nasal gel.

The Phase 2b study design is closely related to the successful 2016 clinical trial, which was funded by the National Institute of Allergy and Infectious Disease (part of the US National Institute of Health) and demonstrated the clinical efficacy of XF-73 versus placebo in reducing nasal *Staphylococcus aureus* carriage in healthy volunteers.

In advance of finalising the Phase 2b design, Destiny Pharma opened an Investigational New Drug (IND) application for XF-73, which is a key regulatory prerequisite for conducting clinical trials in the US. This was followed by the US Food and Drug Administration (FDA) granting Fast Track designation for XF-73, for the prevention of post-surgical staphylococcal infections in March 2018. The clinical programme for XF-73 was further refined following discussions with the FDA and the required Phase 1 dermal safety study, looking at potential skin irritation of XF-73 nasal gel formulation, was completed successfully with XF-73 having a very benign profile with low cumulative irritancy scores similar to the water control. 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 improve further 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.

Destiny Pharma remains confident on the commercial potential of XF-73 nasal gel, especially in US where there is no approved product and XF-73 has been awarded Qualified Infectious Disease Products (QIDP) status from the FDA - a designation given to an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections. The ongoing Phase 2b clinical study has exposed the target product profile to more hospitals and infection control experts and the feedback is encouraging. There have also continued to be independent publications supporting the use of nasal decolonisation for the prevention of post-surgical infections and the clear pharmacoeconomic argument. For example, global and US studies in 2019 have underlined the increase in prevalence of mupirocin resistant *staphylococcal aureus* strains, recommendations that ALL cardiac surgery patients are decolonised prior to surgery and also highlighted the benefits of longer term, post-surgical decolonisation that could be an additional market for XF-73. See references below.

XF-73 dermal infection program and four grant funded research collaborations

In March 2019, Destiny Pharma appointed MedPharm Ltd as its expert partner to develop new topical formulations of the Company's novel XF-platform compounds. During the period, this partnership included developing new formulations of XF-73, for the planned dermal studies for the treatment of infections associated with diabetic foot ulcers and burn wounds, as well as new formulations of XF drugs designed for eye application to target ocular infections. The latter supports the Company's ongoing grant funded research projects.

Work on earlier programmes targeting cystic fibrosis, ventilator associated pneumonia (VAP), ocular infections, biofilms and other indications are being carried out as research projects. Destiny Pharma has now signed four such grant funded research collaborations:

1. Cardiff University: 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 two-year project is examining 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 is being 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 and a team at Tianjin Medical University, China.
2. Aston University: Examining novel compounds from the XF drug platform and 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.
3. Southampton University: The project is examining the use of the Company's 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.
4. Sheffield University: Researching 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.

AMR is a 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 included

discussions and announcements at G7, G20 and United Nations meetings, as well as the World Health Organisation'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. This was reiterated at the World Economic Summit in Davos in January 2019 and are highlighted as key aims under the UK Government's recent announcement of its new 5 and 20 year AMR plan. It was a positive step that both the UK NHS and the US FDA announced new financial incentives in 2019 that have the potential to improve the pricing and market penetration of appropriate new anti-infectives. 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.

References: Dadashi *et al* (2019), Journal of Global Antimicrobial Resistance; Engleman *et al* (2019), Journal of the American Medical Association of Surgery; Huang *et al* (2019), New England Journal of Medicine

Outlook

Destiny Pharma is well funded to develop its lead drug asset, XF-73, through the ongoing Phase 2b clinical programme which has been designed to deliver a robust package for partnering and/or further development into Phase 3, the final stage of clinical development. 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 those caused by MRSA, which is estimated to be over a \$1 billion market opportunity in the US alone.

Four grant awards are also being used to help develop new clinical candidates from the Company's pre-clinical pipeline. The Company is well funded to execute on its business strategy and to progress its lead and follow-on programmes through the planned clinical studies in 2019 and 2020 with a cash runway that extends into 2021. There is continuing international support for the development of novel anti-infective drugs that address the issue of anti-microbial resistance and Destiny Pharma's unique platform is very well-positioned to meet this global need.

Neil Clark
Chief Executive Officer
23 September 2019

Condensed Statement of Comprehensive Income

For the 6 months ended 30 June 2019

	6 months ended 30 June 2019 Unaudited £	6 months ended 30 June 2018 Unaudited £	Year ended 31 December 2018 Audited £
Continuing operations			
Revenue	-	-	-
Administrative expenses	(2,556,773)	(2,035,301)	(5,346,170)
Other operating income	198,474	-	-
Share option charge	(109,454)	(584,726)	(737,687)
Operating loss	(2,467,753)	(2,620,027)	(6,083,857)
Finance income	40,316	36,960	75,999
Loss before tax	(2,427,437)	(2,583,067)	(6,007,858)
Income Tax	332,413	306,458	841,144
Loss for the period	(2,095,024)	(2,276,609)	(5,166,714)
Other comprehensive income	-	-	-
Total comprehensive loss from continuing operations	(2,095,024)	(2,276,609)	(5,166,714)

Loss per share (Note 5)

Basic and diluted	(4.8)p	(5.2)p	(11.9)p
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Condensed Statement of Financial Position

For the 6 months ended 30 June 2019

	As at 30 June 2019 Unaudited £	As at 30 June 2018 Unaudited £	As at 31 December 2018 Audited £
ASSETS			
Non-current assets			
Property, plant and equipment (Note 6)	38,031	29,548	30,421
Current assets			
Trade and other receivables	1,259,349	634,020	930,759
Prepayments and accrued income	186,157	38,055	36,406
Cash and cash equivalents	5,077,954	11,060,904	7,060,821
Other financial assets	4,000,000	4,000,000	5,000,000
Current assets	10,523,460	15,732,979	13,027,986
TOTAL ASSETS	10,561,491	15,762,527	13,058,407
EQUITY AND LIABILITIES			
Current liabilities			
Trade and other payables	283,367	768,768	801,792
Current liabilities	283,367	768,768	801,792

Shareholders' equity

Issued share capital (Note 7)	438,652	435,626	435,626
Share premium	17,296,337	17,292,284	17,292,284
Accumulated losses	(7,456,865)	(2,734,151)	(5,471,295)
Total shareholders' equity	(10,278,124)	14,993,759	12,256,615
TOTAL EQUITY AND LIABILITIES	10,561,491	15,762,527	13,058,407

Condensed Statement of Changes in Equity
For the 6 months ended 30 June 2019

	Issued share capital £	Share premium £	Accumulated losses £	Total £
As at 1 January 2019	435,626	17,292,284	(5,471,295)	12,256,615
Total comprehensive loss	-	-	(2,095,024)	(2,095,024)
Share option charge	-	-	109,454	109,454
Issue of share capital	3,026	4,053	-	7,079
As at 30 June 2019	438,652	17,296,337	(7,456,865)	10,278,124

	Issued share capital £	Share premium £	Accumulated losses £	Total £
As at 1 January 2018	435,626	17,292,284	(1,042,268)	16,685,642
Total comprehensive loss	-	-	(2,276,609)	(2,276,609)
Share option charge	-	-	584,726	584,726
As at 30 June 2018	435,626	17,292,284	(2,734,151)	14,993,759

	Issued share capital £	Share premium £	Accumulated losses £	Total £
As at 1 January 2018	435,626	17,292,284	(1,042,268)	16,685,642
Loss and total comprehensive loss for the period	-	-	(5,166,714)	(5,166,714)
Share option charge	-	-	737,687	737,687
As at 31 December 2018	435,626	17,292,284	(5,471,295)	12,256,615

Condensed Statement of Cash Flows
For the 6 months ended 30 June 2019

	6 months ended 30 June 2019 Unaudited £	6 months ended 30 June 2018 Unaudited £	Year ended 31 December 2018 Audited £
Cash flows from operating activities			
Loss before income tax	(2,427,437)	(2,583,067)	(6,007,858)
Depreciation charges (note 6)	8,868	3,850	9,663
Share option charge	109,454	584,726	737,687
Finance income	(40,316)	(36,960)	(75,999)
(Increase)/decrease in trade and other receivables and prepayments	(145,928)	(28,849)	(23,162)
Increase/(decrease) in trade and other payables	(518,425)	371,292	404,317
Taxation received	-	-	233,908
Net cash outflow from operating activities	(3,013,784)	(1,689,008)	(4,721,444)
Cash flows from investing activities			
Purchase of tangible fixed assets	(16,478)	(11,085)	(17,771)
Maturity of other financial assets	5,000,000	5,000,000	-
Purchase of other financial assets	(4,000,000)	(4,000,000)	-
Interest received	40,316	36,960	75,999
Net cash flow from investing activities	1,023,838	1,025,875	58,228
Cash flows from financing activities			
New shares issued net of issue costs	7,079	-	-
Net cash inflow from financing activities	7,079	-	-
Net decrease in cash and cash equivalents	(1,982,867)	(633,133)	(4,663,216)
Cash and cash equivalents at the beginning of the period	7,060,821	11,724,037	11,724,037
Cash and cash equivalents at the end of the period	5,077,954	11,060,904	7,060,821

Notes to the Condensed Financial Statements

1. General Information

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

Destiny 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

These interim unaudited financial statements have been prepared in accordance with AIM Rule 18, 'Half yearly reports and accounts'. The financial information contained in these interim financial statements have been prepared under the historical cost convention and on a going concern basis. The interim financial information for the six months ended 30 June 2019 and for the six months ended 30 June 2018 contained within this interim report do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006.

In the opinion of the Directors, the interim consolidated financial information presents fairly the financial position, and results from operations and cash flows for the period. Comparative amounts for the six months ended 30 June 2018 are also unaudited.

The interim financial statements for the six months ended 30 June 2019 were approved by the Board on 20 September 2019.

3. Accounting Policies

The unaudited interim financial statements for the period have been prepared on the basis of the accounting policies adopted in the audited report and accounts of the Company for the year ended 31 December 2018 and expected to be adopted in the financial year ending 31 December 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 unaudited interim financial statements and no adjustments were required as a consequence of its adoption.

4. Segmental Information

The chief operating decision-maker is considered to be the Board of Directors of Destiny. 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 Destiny has one operating segment, the development and commercialisation of pharmaceutical formulations.

Geographical Segments

The Company's only geographical segment during the period was the UK.

5. Loss Per 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:

	6 months ended 30 June 2019 Unaudited £	6 months ended 30 June 2018 Unaudited £	Year ended 31 December 2018 Audited £
Loss for the period from continuing operations	(2,095,024)	(2,276,609)	(5,166,714)
Weighted average number of shares	43,733,614	43,562,598	43,562,598
Loss per share - pence			
Basic and diluted	(4.8)p	(5.2)p	(11.9)p

6. Property, plant and equipment

	Plant and machinery £
Cost	
At 1 January 2019	97,147
Additions	16,478
At 30 June 2019	113,625
Depreciation	
At 1 January 2019	66,726
Charge for the period	8,868
At 30 June 2019	75,594
Net book value at 30 June 2019	38,031

	Plant and machinery £
Cost	
At 1 January 2018	79,376
Additions	11,085
At 30 June 2018	90,461
Depreciation	
At 1 January 2018	57,063
Charge for the period	3,850
At 30 June 2018	60,913
Net book value at 30 June 2018	29,548

Property, plant and equipment (contd.)

	Plant and machinery £
Cost	
At 1 January 2018	79,376
Additions	17,771
At 31 December 2018	97,147
Depreciation	
At 1 January 2018	57,063
Charge for the year	9,663
At 31 December 2018	66,726
Net book value at 31 December 2018	30,421

7. Share capital

During the period 302,597 Ordinary shares were issued pursuant to the exercise of share options by certain former employees.

On 4 June 2019, 200,000 Employee LTIP Options were granted to Neil Clark and 75,000 Employee LTIP Options were granted to Jesus Gonzalez. These options have been granted at a price of £0.01 per ordinary share which will vest on the third anniversary of the date of grant and are exercisable for ten years thereafter.

On 4 June 2019 45,000 Employee LTIP EMI Options and 15,000 Employee LTIP Options were granted to certain senior employees. These options have been granted at a price of £0.01 per ordinary share which will vest on the third anniversary of the date of grant and are exercisable for ten years thereafter.

8. Events after the end of the reporting period

There are no events subsequent to the reporting period that require adjustment or disclosure.

9. Copies of the interim financial statements

Copies of these interim unaudited financial statements are available on the Company's website at www.destinypharma.com and from the Company's registered office, Unit 36 Sussex Innovation Centre Science Park Square, Falmer, Brighton, BN1 9SB

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