Interim results for the 6 months ended 30 Jun 2020

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Destiny Pharma PLC
17 September 2020

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

Interim results for the six months ended 30 June 2020

Lead product to prevent post-surgical infections in Phase 2b clinical trial

Recruitment planned to complete by end of 2020; results expected in Q1 2021

Grant funded COVID-19 collaboration announced

Company funded to Q4 2021

Brighton, United Kingdom - 17 September 2020 - Destiny Pharma (AIM: DEST), a clinical stage biotechnology company focused on the development of novel products to prevent life threatening infections, announces its unaudited interim financial results for the half-year ended 30 June 2020 and an update for the year to date.

Operational highlights

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

- Protocol amendment agreed with FDA and Phase 2b XF-73 nasal study size revised to 125 patients with recruitment planned to complete by end of 2020
- Quality of study and statistical quality of Phase 2b not affected by reduction in size
- Positive interim safety analysis of Phase 2b trial performed by independent data monitoring committee
- Good recruitment momentum post COVID-19 delays. Refer to separate Clinical Update announced today

Financial highlights

- Strong cash position with cash and term deposits at 30 June 2020 of £5.6 million (30 June 2019: £9.1 million; 31 December 2019: £7.5 million)
- Expenditure on R&D in the period of £2.3 million (half-year 2019: £1.7 million; full year 2019: £3.8 million) reflecting the increased investment in clinical research
- Company funded through to Q4 2021

SporeGen COVID-19 collaboration

- Destiny Pharma and SporeGen announced collaboration and Innovate UK grant award of £800,000 to co-develop a novel, preventative product for COVID-19
- Expands Destiny Pharma's novel pipeline targeted at preventing infections with novel biologics/microbiome approach

Earlier pipeline and research projects

- Research projects with Cardiff, Sheffield, Southampton and Aston Universities making progress after COVID-19 delays
- New grant awarded by National Biofilms Innovation Centre (NBIC) to fund a second research collaboration with Cardiff University in oral infections
- Oxford University review supports the unique target profile of XF-73 and its potential to address the threat of anti-microbial resistance (AMR)

Neil Clark, CEO of Destiny Pharma, commented:

"Destiny Pharma has made great progress in 2020. We agreed a protocol amendment with the US FDA and announced a good interim safety review on our important Phase 2b study of our lead drug candidate, XF-73, for the prevention of post-surgical hospital infections. We now look forward to completing patient recruitment by the end of 2020 and announcing results in Q1 2021. This is the major value driver for the company.

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 pipeline of unique infection prevention products has recently been expanded with SPOR-COV, a novel, preventative treatment for

COVID-19. This product is being co-developed with SporeGen Ltd and supported by an £800,000 Innovate UK grant.

COVID-19 has highlighted vividly the healthcare impact of infectious disease and we are convinced that Destiny Pharma's unique pipeline has the potential to deliver novel commercially attractive products to prevent life threatening infections."

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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 that can prevent life threatening infections. 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 Organization (WHO) and the United Nations, as well as the G7 and the G20 countries. Destiny Pharma is also collaborating with SporeGen® to co-develop a novel, preventative product for COVID-19. 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 summary

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 and therefore have significant potential to address the global threat of anti-microbial resistance (AMR).

XF-73 has been shown to kill bacteria very rapidly and is planned to be an effective new treatment in the reduction of bacterial infections in hospital patients after surgery, 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. There is currently no approved product in the US for the reduction of post-surgical staphylococcal infections although approximately a third of all patients have nasal *Staphylococcal aureus* carriage as they enter surgery.

This strong clinical 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 commercial plans for XF-73 nasal gel as a new hospital product in a poorly served multi-billion dollar market.

The addition of SPOR-COV, a COVID-19 preventative treatment, to our pipeline through a new collaboration with SporeGen Limited is confirmation of our strategy to enlarge our pipeline and is an exciting move into the biologicals/microbiome sector. The potential of this asset was validated by the concurrent award of an
£800,000 Innovate UK grant.

Phase 2b clinical trial

The Phase 2b clinical study is recruiting patients undergoing open heart surgery in United States and Europe and has now recruited 88 patients out of the target of 125. Barring any further impact from COVID-19 the study is on plan to complete recruitment by the end of 2020 and report results in Q1 2021.

In July, Destiny Pharma agreed a protocol amendment with the FDA that reduced the size of the study and also reported excellent interim safety data. Importantly the reduced size of the study does not compromise its integrity, statistical relevance or clinical objectives.

The agreed protocol amendment recognised the impact COVID-19 has had in slowing patient recruitment in clinical studies since March and the FDA's willingness to support certain protocol amendments that help to accelerate the completion of ongoing clinical trials but do not compromise a study's integrity and clinical objectives. The amendment to the protocol incorporated a change to the primary patient population where the primary endpoint for the study will be measured. The primary microbiological endpoint post-surgery is now being measured in patients who have a positive load of nasal *Staphylococcus aureus* before receiving the study treatment. This contrasts to the original primary population, which included all randomised patients regardless of their baseline nasal load of *Staphylococcus aureus*. Very importantly, this change enabled a reduction in the defined study size from 200 patients to 125 while maintaining the statistical power of the study and its clinical value. This preserved the potential of the trial results to be a key step towards the Phase 3 clinical trial programme of XF-73. Other protocol modifications agreed with the FDA regarding study procedures will also make it easier for hospitals to recruit and retain hospital patients

An interim safety review was completed by an Independent Data Monitoring Committee (IDMC) of the Phase 2b study. The committee reviewed safety data from the first 75 patients who completed study treatment. Adverse event data, including safety laboratory results, incidence of post-operative infections, ear, nose, and throat examinations, as well as sense of smell tests were reviewed by the IDMC. Based on their evaluation, the IDMC recommended that the study could continue without any modifications to the protocol.

SPOR-COV - a new COVID-19 project

Earlier this month Destiny Pharma entered into a collaboration agreement with SporeGen Limited to co-develop SporeGen's SPOR-COV product as a novel, preventative treatment for COVID-19.

Under the agreement, the parties will share any costs and commercial returns from SPOR-COV and plan to complete a pre-clinical programme with the aim of being ready to enter the first human clinical trials within 18 months.

The SPOR-COV product consists of a proprietary formulation of *Bacillus* bacteria that will be administered nasally as a spray. SPOR-COV has already been shown by SporeGen to provide complete (100%) protection in preclinical models of influenza virus.

SPOR-COV is different to vaccines in that it utilises the innate immune system with the aim of developing COVID-19 protection a few days after dosing. As an "easy to use" first line of defence, it has the potential to reduce COVID-19 infection rates and transmission significantly. The final SPOR-COV product is planned to be straightforward to produce at high volumes and at low cost. It can also be stockpiled almost indefinitely without the need for cold chain refrigeration. It could be made available globally as a cost-effective measure in the fight against COVID-19 as well as new COVID strains and other respiratory viral infections.

The SPOR-COV programme is supported by an Innovation UK grant of £800,000 which will fund the majority of the £1 million cost of the initial SPOR-COV programme.

XF Research update

The Company's earlier pipeline is largely funded through non-dilutive grant funding. These projects are looking at the utility of XF compounds in preventing and/or treatment of infections in ocular, respiratory, dermal and oral indications. Progress on these projects has been slowed due to COVID-19 and the associated restrictions on University based laboratory work but activity is planned to increase in the last quarter of 2020.

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The pipeline was expanded further in in the first half of 2020 as Destiny Pharma was jointly awarded a National Biofilms Innovation Centre (NBIC) grant to fund a research collaboration with Cardiff University. The project will establish the potential of three of the Company's proprietary XF drug compounds, DPD-207, XF-70 and XF-73 as novel treatments for clinically important fungal infections in mucosal mouth models of disease.

The promising no/low resistance profile of XF-73 was supported by the publication of a new independent paper in Trends in Microbiology, entitled: *"Assessing the potential for Staphylococcus aureus to evolve resistance to XF-73".*

The review looked at data from a number of established microbiology models that were used to evaluate the action of XF-73 in killing *S. aureus* that were carried out previously by Destiny Pharma. The paper concluded that the available evidence suggests that *S. aureus* has low potential to evolve resistance to XF-73 relative to antibiotics. This conclusion supports the Company's own view that XF-73 has a unique resistance profile due to its novel, ultra-fast mechanism of action that is a key advantage compared to typical antibiotics.

Outlook

Destiny Pharma is well funded to complete the Phase 2 clinical development of its lead drug asset, XF-73. The Company is currently designing the Phase 3 clinical study that will hopefully follow. Importantly, market analysis supports 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.

Six grant awards worth over £2.5 million have been awarded to Destiny Pharma projects since 2018 and are being used to help develop new clinical candidates from the Company's XF pipeline and the SPOR-COV project. This demonstrates the potential value in Destiny's growing 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 2020 with a cash runway that extends to Q4 2021.

There is increased 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. The significant healthcare and economic impact of COVID-19 has highlighted clearly the global need for innovation that delivers fast, safe and affordable anti-infection treatments.

Neil Clark
Chief Executive Officer
17 September 2020

Condensed Statement of Comprehensive Income
For the 6 months ended 30 June 2020

	6 months ended 30 June 2020 Unaudited £	6 months ended 30 June 2019 Unaudited £	Year ended 31 December 2019 Audited £
Continuing operations			
Revenue	**-**	-	-
Administrative expenses	**(2,912,801)**	(2,556,773)	(5,687,003)
Other operating income	**12,450**	198,474	305,906
Share option charge	**(58,668)**	(109,454)	(203,655)
Operating loss	**(2,959,019)**	(2,467,753)	(5,584,752)
Finance income	**13,470**	40,316	63,478
Loss before tax	**(2,945,549)**	(2,427,437)	(5,521,274)
Income Tax	**515,378**	332,413	813,250
Loss for the period	**(2,430,171)**	(2,095,024)	(4,708,024)
Other comprehensive income	**-**	-	-
Total comprehensive loss from continuing operations	**(2,430,171)**	(2,095,024)	(4,708,024)
Loss per share (Note 5)			
Basic and diluted	**(5.5)p**	(4.8)p	(10.7)p

Condensed Statement of Financial Position
For the 6 months ended 30 June 2020

	As at 30 June 2020 Unaudited £	As at 30 June 2019 Unaudited £	As at 31 December 2019 Audited £
ASSETS			
Non-current assets			
Property, plant and equipment (Note 6)	**25,764**	38,031	32,922
Current assets			
Trade and other receivables	**559,747**	1,259,349	911,198
Prepayments and accrued income	**48,192**	186,157	133,702
Cash and cash equivalents	**5,571,631**	5,077,954	7,479,642
Other financial assets	**-**	4,000,000	-
Current assets	**6,179,570**	10,523,460	8,524,542
TOTAL ASSETS	**6,205,334**	10,561,491	8,557,464
EQUITY AND LIABILITIES			
Current liabilities			
Trade and other payables	**817,512**	283,367	798,139
Current liabilities	**817,512**	283,367	798,139
Shareholders' equity			
Issued share capital (Note 7)	**438,652**	438,652	438,652
Share premium	**17,296,337**	17,296,337	17,296,337
Accumulated losses	**(12,347,167)**	(7,456,865)	(9,975,664)
Total shareholders' equity	**5,387,822**	10,278,124	7,759,325
TOTAL EQUITY AND LIABILITIES	**6,205,334**	10,561,491	8,557,464

Condensed Statement of Changes in Equity

For the 6 months ended 30 June 2020

	Issued share capital £	Share premium £	Accumulated losses £	Total £
As at 1 January 2020	438,652	17,296,337	(9,975,664)	7,759,325
Loss and total comprehensive loss for the period	-	-	(2,430,171)	(2,430,171)
Share based payment expense	-	-	58,668	58,668
As at 30 June 2020	438,652	17,296,337	(12,347,167)	5,387,822

	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 and loss for the period	-	-	(2,095,024)	(2,095,024)
Issue of share capital	3,026	4,053		7,079
Share based payment expense	-	-	109,454	109,454
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 2019	435,626	17,292,284	(5,471,295)	12,256,615
Loss and total comprehensive loss for the period			(4,708,024)	(4,708,024)
Issue of share capital	3,026	4,053	-	7,079
Share based payment expense	-	-	203,655	203,655
As at 31 December 2019	438,652	17,296,337	(9,975,664)	7,759,325

Condensed Statement of Cash Flows
For the 6 months ended 30 June 2020

	6 months ended 30 June 2020 Unaudited £	6 months ended 30 June 2019 Unaudited £	Year ended 31 December 2019 Audited £
Cash flows from operating activities			
Loss before income tax	**(2,945,549)**	(2,427,437)	(5,521,274)
Depreciation charges (note 6)	**9,017**	8,868	18,440
Share based payment expense	**58,668**	109,454	203,655
Finance income	**(13,470)**	(40,316)	(63,478)
Decrease/(increase) in trade and other receivables and prepayments	**113,260**	(145,928)	(79,800)
Increase/(decrease) in trade and other payables	**19,373**	518,425	(3,653)
Tax received	**839,079**	-	815,316
Net cash used in operating activities	**(1,919,622)**	(3,013,784)	(4,630,794)
Cash flows from investing activities			
Purchase of tangible fixed assets	**(1,859)**	(16,478)	(20,942)
Maturity of other financial assets	**-**	5,000,000	5,000,000
Purchase of other financial assets	**-**	(4,000,000)	-
Interest received	**13,470**	40,316	63,478
Net cash flow from investing activities	**11,611**	1,023,838	5,042,536
Cash flows from financing activities			
New shares issued net of issue costs	**-**	7,079	7,079
Net cash inflow from financing activities	**-**	7,079	7,079
Net decrease in cash and cash equivalents	**(1,908,011)**	(1,982,867)	418,821
Cash and cash equivalents at the beginning of the period	**7,479,642**	7,060,821	7,060,821
Cash and cash equivalents at the end of the period	**5,571,631**	5,077,954	7,479,642

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 2020 and for the six months ended 30 June 2019 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 2019 are also unaudited.

The interim financial statements for the six months ended 30 June 2020 were approved by the Board on 16 September 2020.

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 2019 and expected to be adopted in the financial year ending 31 December 2020.

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 2020 Unaudited £	**6 months ended 30 June 2019 Unaudited £**	Year ended 31 December 2019 Audited £
Loss for the period from continuing operations	(2,430,171)	(2,095,024)	(4,708,024)
Weighted average number of shares	43,865,195	43,733,614	43,799,945
Loss per share - pence			
Basic and diluted	(5.5)p	(4.8)p	(10.7)p

6. Property, plant and equipment

	Plant and machinery £
Cost	
At 1 January 2020	118,089
Additions	1,859
At 30 June 2020	**119,948**

Depreciation	
At 1 January 2020	85,167
Charge for the period	9017
At 30 June 2020	**94,184**
Net book value at 30 June 2020	**25,764**

	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**

Property, plant and equipment (contd.)

	Plant and machinery £
Cost	
At 1 January 2019	97,147
Additions	20,942
At 31 December 2019	**118,089**
Depreciation	
At 1 January 2019	66,726
Charge for the year	18,440
At 31 December 2019	**85,167**
Net book value at 31 December 2019	**32,922**

7. Share capital

On 18 June 2019, 150,000 Employee LTIP options in respect of Shaun Claydon were cancelled.

On 19 June 2019, 125,000 Employee LTIP Options were granted to Shaun Claydon and 40,000 Employee LTIP Options were granted to Jesus Gonzalez. These options have been granted at a price of £0.01 per ordinary share and for Shaun Claydon the Options will vest on 26 October 2021. The options granted to Jesus Gonzales will vest on the third anniversary of the date of grant. Both Option grants are exercisable for ten years after the date of grant.

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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