# Audited results for year ended 31 December 2021

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**Destiny Pharma plc**

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

**Audited results for the year ended 31 December 2021**

*Good progress preparing NTCD-M3 Phase 3 programme targeting C. difficile infection recurrence*

*Discussions continue to progress with potential licensing partners for NTCD-M3*

*Primary endpoint met in XF-73 nasal Phase 2b clinical study*

*Secondary endpoint data showed XF-73 nasal exhibited a significant and sustained nasal reduction of S.aureus*

*Positive feedback from European Medicines Agency on XF-73 nasal Phase 3 programme design*

*£6.5M post period equity fundraise completed - Company funded through to mid-2023*

**Brighton, United Kingdom - 12 April 2022 -** Destiny Pharma plc (AIM: DEST), a clinical stage innovative biotechnology company focused on the development of novel medicines that can prevent life-threatening infections, announces its audited financial results for the year ended 31 December 2021.

**Financial and corporate highlights**

- Loss before tax of £6.3 million (2020: £6.5 million)
- R&D expenditure of £3.7 million (2020: £4.5 million)
- Other operating expenses (excluding share based payment charge) of £2.3 million (2020: £1.9 million)
- Year-end cash and cash equivalents of £4.6 million (2020: £9.7 million)
- Post period equity fund raise of £6.5 million
- Cash runway extended to mid-2023

**Operational highlights**

***NTCD-M3 for prevention of C. difficile infection recurrence***

- Good progress made during the year with the transfer and commencement of manufacturing scale up processes and advancement of discussions with US and European regulators on finalising the detail of the Phase 3 clinical trial design. Regulatory discussions are expected to conclude in the first half of 2022, manufacturing scale up by year-end and the Phase 3 trial is targeted to commence thereafter.
- Discussions are progressing with potential licencing partners, with several parties active in the data room. This is in line with the Company's strategy of seeking partners to co-fund Phase 3 trials and lead commercialisation of the asset.
- US Department of Veterans Affairs research study confirms the potential of NTCD-M3 as a novel treatment to prevent the recurrence of C. difficile infections (CDI) that can be used alongside all standard-of-care antibiotic treatments.
- US and European market research underpins clinical support and market potential of NTCD-M3.
- Establishment of a NTCD-M3 clinical advisory board consisting of Professor Dale Gerding MD, US, who discovered NTCD-M3, Professor Mark Wilcox MD, UK key opinion leader in CDI and other medical and drug development experts with recent experience of running and designing international Phase 3 clinical studies in CDI.

***XF-73 nasal gel for prevention of post-surgical infections***

- Positive top-line results in Phase 2b clinical study reported in 2021. Primary efficacy endpoint met successfully with high statistical significance and no treatment related safety events.

- Very good secondary endpoint data announced in August 2021 showed that XF-73 has the potential to keep patients at a significantly low *S. aureus* nasal burden during the period of highest infection risk which runs from 1 hour prior to incision, during surgery itself, to the start of wound healing and out to 6 days post-surgery.

- Independent European report underpins the clinical need and market opportunity of XF-73 nasal gel which is seen as a very promising alternative to the current standard of care, Mupirocin, by both clinicians and payers.

- Successful XF-73 nasal gel Phase 2b study data was presented at 2021 ECCMID (European Congress of Clinical Microbiology & Infectious Diseases) Congress by infection prevention expert, Professor Julie Mangino MD.

***Earlier pipeline and research projects***

- Two new collaborations signed: NIAID in US supporting XF-73 dermal infection programme and US Department of Veterans Affairs to research NTCD-M3 for prevention of recurrence of CDI.

- Pre-clinical work on SporCov COVID-19 programme in collaboration with joint partner SporGen Limited (which is largely funded by an £0.8 million Innovate UK grant) completing in H1 2022. Plans for next stage of development are being progressed.

- XF platform research projects are progressing well after Covid-19 delays and are largely funded by grants and non-dilutive funding.

***Post period highlights***

- Positive feedback received from the European Medicines Agency (EMA) on plans for XF-73 nasal gel Phase 3 programme design. Phase 3 can use a similar primary endpoint to the successful Phase 2b clinical study, providing a route through Phase 3 trials to the European approval of XF-73 nasal gel as a ground breaking hospital infection prevention product. Feedback from FDA is expected in Q2 2022.

- Successful completion of the first of two pre-clinical safety studies of XF-73 Dermal formulation. Work continues with US Government's NIAID to complete preclinical safety package that will support future clinical development of XF-73 Dermal in serious wound infections.

- China Medical System Holdings Limited (CMS), the Company's China regional partner and investor, started an additional dermal programme with XF-73 targeting the prevention and treatment of superficial skin infections caused by bacteria.

- Successful equity fund raise of £6.5 million (gross) to enable continued progress of NTCD-M3 and XF73 nasal toward Phase 3 clinical studies, finalisation of regulatory plans and strengthening of balance sheet.

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

"With full control of two high quality, late-stage clinical assets targeted at infection prevention, both of which are backed by strong Phase 2 clinical data and clear commercial positioning, Destiny Pharma is very well positioned for the future. We have made excellent progress in developing our pipeline in 2021 and the Board and employees are excited about delivering on our strategy to build a world leading infection prevention company."

**Webcast**

Destiny Pharma will host a webcast presentation followed by a live Q&A session at 10:30 am BST today, accessible via the Investor Meet Company platform.

The webcast of the presentation will be available on the Company's investor relations website at www.destinypharma.com. The presentation is open to analysts and all existing and potential new shareholders.

Investors can sign up to Investor Meet Company for free, and add to meet **Destiny Pharma plc** via:
https://www.investormeetcompany.com/destiny-pharma-plc/register-investor. Investors who already follow Destiny Pharma plc on the Investor Meet Company platform will automatically be invited.

This announcement has been released by Shaun Claydon, Chief Financial Officer (CFO), on behalf of the Company.

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**About Destiny Pharma**
Destiny Pharma is a clinical stage, innovative biotechnology company focused on the development of novel medicines that can prevent life-threatening infections. Its pipeline has novel microbiome-based biotherapeutics and XF drug clinical assets including NTCD-M3, a Phase 3 ready treatment for the prevention of *C. difficile* infection (CDI) recurrence which is the leading cause of hospital acquired infection in the US and XF-73 nasal gel, which has recently completed a positive Phase 2b clinical trial targeting the prevention of post-surgical staphylococcal hospital infections including MRSA. It is also co-developing SPOR-COV, a novel, biotherapeutic product for the prevention of COVID-19 and other viral respiratory infections and has earlier grant funded XF research projects.

For further information, please visit 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 and strategic review

Our pipeline has a much reduced risk profile compared to many other biotechnology companies as our two lead assets have both completed Phase 2 and have been shown to be effective and safe. They also act through two completely different mechanisms, reducing the risk in the pipeline through clear diversification.

The Company's lead drug candidate, NTCD-M3 for the prevention of CDI, is focused on infection prevention and is very well positioned as a targeted, naturally occurring bacterial therapy for this serious gut infection. The NTCD-M3 programme also brings the Company into the exciting area of the human microbiome and biotherapeutics, which is a fast-developing area of medical science and investigation for new therapies.

We believe that XF-73 nasal, our other late-stage programme and the lead drug candidate from our XF platform, has a target product profile that is very attractive to hospital infection experts. There are many millions of hospital operations in the US alone where a new drug is needed to help prevent post-surgical infections.

### NTCD-M3 *Clostridioides difficile* programme

NTCD-M3 was developed by gastrointestinal infection (GI) physician Professor Dale Gerding, who is a world-leading specialist in *C. difficile*, with more than 400 peer-reviewed journal publications, book chapters and review articles in the area. NTCD-M3 has successfully completed Phase 1 and Phase 2b trials. The Phase 1 study demonstrated a strong safety/toxicology profile and the 95% prevention of CDI recurrence. Phase 2b NTCD-M3 data was published in the prestigious Journal of the American Medical Association (Gerding DN et al JAMA 2015;313:1719).

NTCD-M3 has also been awarded Fast Track status by the FDA. Destiny Pharma acquired global rights to the NTCD-M3 programme in November 2020.

### NTCD-M3 mechanism of action harnesses the human microbiome

NTCD-M3 is a naturally occurring non-toxigenic strain of *C. difficile* bacteria, which lacks the genes that can express *C. difficile* toxins. It is an oral formulation of NTCD-M3 spores and patients who have taken NTCD-M3 were found to be protected from *C. difficile* infections. NTCD-M3 acts as a safe "ground cover" preventing toxic strains of *C. difficile* proliferating in the colon after antibiotic treatment. NTCD-M3 temporarily colonises the human gut without causing any symptoms and the gut microbiome returns to normal a few weeks after treatment.

The Phase 2 data from a completed study with NTCD-M3 was very promising. The study was a randomised, double-blind, placebo-controlled trial, among 173 patients aged >18 years, who were diagnosed as having CDI (either a first episode or first recurrence). The results were a strong, statistically significant data set showing rapid onset of colonisation which provided protection during the early post-treatment period, making it an ideal complement to a vaccine and other antibiotic treatments. The rate of recurrence (RR) of CDI after treatment with the best dose of NTCD-M3 was only 5%, (placebo 30%) $p<0.01$. The Company believes this is compelling efficacy compared with clinical trial data from other approaches.

The Company has held discussions with the FDA as part of Type C meetings and this clarified the work required to prepare for Phase 3 clinical trials including certain manufacturing scale-up activities that are important for such a late-stage clinical project and also the detailed Phase 3 design. The FDA meeting confirmed that a single Phase 3 800 patient study is required as a randomised, double-blind, placebo-controlled trial.

The treatment regimen will be an oral capsule of an NTCD-M3 dose of $10^7$ spores (or placebo) once daily for seven days starting after the last antibiotic course.

Sampling will take place to confirm NTCD-M3 colonisation, assess changes in the faecal microbiome during treatment with NTCD-M3 and the recurrence rate of CDI. The plan is to complete the manufacturing tech transfer and set-up in 2022 and, subject to funding, start Phase 3 recruitment as soon as possible in 2023 and finish in 2025.

The Company has undertaken market research to assess the US market size for prevention of recurrence indication. The only approved drug is Merck's Zinplava that is expensive and reimbursed at c.US$3,700, which inhibits its uptake. It is expected that NTCD-M3 could be priced at US$1,500, delivering estimated peak US sales of c.US$200 million. The market for Europe and the rest of the world is estimated by Destiny Pharma to be a similar size, so global sales per annum of c.US$500 million could be achieved. There is also the potential for additional indications (prevention /multiple recurrence) that could double the global peak sales to c.US$1 billion per annum. The extra costs of care in the US per CDI patient range from US$10,000 to 20,000 and the total annual CDI-attributable cost in the US alone was estimated in 2016 at US$6.3 billion. Total annual CDI hospital management required nearly 2.4 million days of inpatient stay. This is a significant burden on the US healthcare system.

### XF platform

The XF platform presents the opportunity to deliver "prevention rather than cure" at sensible pricing whilst delivering safe, effective anti-infective treatments that also address the issue of AMR.

The Board believes that increasing governmental pressure and financial incentives that are being implemented by leading institutions such as the WHO, UN, FDA and G7/G20 will further increase the options available for profitable commercialisation and the generation of shareholder value. The UK and US governments have been taking the lead here by introducing new regulations with clear financial incentives that may be available for novel anti-infectives such as those being developed by Destiny Pharma.

### The key potential benefits of the XF platform are significant:

- Ultra-rapid bacteria kill: Studies have shown the XF drugs killing bacteria *in vitro* in less than 15 minutes; faster acting than standard antibiotics currently in use;
- Ability to kill bacteria in any growth phase: This is an important feature as bacteria are not always actively growing. XF drugs can kill bacteria even when dormant;
- Ability to kill bacteria within bacterial biofilms: Biofilms are an increasing problem that are poorly treated by current drugs as they act as a protective barrier for bacteria. They are associated with indwelling medical devices;
- Active against all Gram-positive bacteria tested to date and selected Gram-negative bacteria: This includes clinically important and infection-causing strains, such as: *Staphylococcus aureus, Listeria monocytogenes, Propionibacterium acnes,* Group G *Streptococcus, Mycobacterium tuberculosis, Streptococcus pneumonia, Bacillus anthracis, Yersinia pestis, Acinetobacter baumannii, Pseudomonas aeruginosa*, and *Clostridium difficile*; and
- No bacterial (MRSA) resistance is seen to emerge: No bacterial (MRSA) resistance was seen to emerge in a landmark *in vitro* study of bacterial resistance that compared XF-73 to standard antibiotics currently in use.

### Clinical data underpinning the XF-73 nasal programme is strong

The announcement of positive Phase 2b results in 2021 confirmed the potential of XF-73 nasal gel, XF-73 (exeporfinium chloride)

The announcement of positive Phase 2b results in 2021 confirmed the potential of XF-73 nasal gel XF-73 (oxyquinolin chloride) was awarded Qualified Infectious Disease Product ("QIDP") status by the FDA in 2015. Within the QIDP award, the FDA also confirmed a new US disease indication for XF-73 nasal; namely the "prevention of post-surgical staphylococcal infections", including MRSA. This represents a new US market for which no existing product is approved.

QIDP status identifies XF-73 nasal as a drug that is intended to treat serious or life-threatening infections, including those caused by antibiotic resistant pathogens. The FDA also awarded XF-73 nasal Fast Track status in 2019, recognising it as a priority drug for US development.

Destiny Pharma has now completed seven successful clinical trials in over 300 subjects with XF-73 nasal, which included measures of its efficacy in reducing nasal colonisation by *Staphylococcus aureus*.

The Phase 2b study completed in 2021 was a multi-centre, randomised, placebo-controlled study of multiple applications of a single concentration of XF-73 nasal gel to assess the antimicrobial effect of XF-73 nasal on commensal *Staphylococcus aureus* nasal carriage in patients scheduled for surgical procedures.

Destiny Pharma's experience in carrying out this clinical study has confirmed the increasing compliance in US hospitals with best practice, whereby patients are screened, and carriers of *Staphylococcus aureus* are decolonised prior to surgery. This is very supportive of the potential sales in the initial market for XF-73 nasal gel in the large US hospital surgery market.

**Efficacy conclusion - very strong Phase 2b data supporting XF-73 nasal target product profile ("TPP")**

- XF-73 reduced the mean nasal burden of *S. aureus* in patients undergoing open chest open heart surgery by 2.5 log (99.5% reduction) in the 24 hours immediately before surgery in the micro-ITT population. The effect was maintained during surgery - considered the period when the risk for infections is the highest.
- XF-73 showed 2.1 log (99.2%) greater reduction than placebo in the same patient population and this difference in reduction of nasal burden of *S. aureus* was statistically significant ($p<0.0001$) in both the micro-ITT and per protocol populations.
- A significantly higher reduction of burden of nasal *S. aureus* in XF-73 arm compared to placebo arm in the 24 hours before surgery was also observed when the data was analysed by AUC. This higher reduction was also seen when analysing the percentage of patients reaching a specific log value over time.

The Company is in the process of finalising Phase 3 study designs for XF-73 nasal and is seeking scientific advice from the key regulators in the US and Europe. It is expected that these regulatory discussions will be completed mid-2022. Destiny Pharma will then be able to establish the size and costs of the Phase 3 studies and with that information a targeted partnering campaign will begin with the aim of finding one or more partners in H1 2023 or sooner if possible.

**The medical need to combat surgical infections is significant**

Patient carriage of *Staphylococcus aureus* strains, including MRSA, is recognised as a growing problem and the testing of patients entering hospital for surgery is widespread in many countries, including the US. Landmark outcome studies (Bode et al 2010) have demonstrated that reduction of all strains of *Staphylococcus aureus* can significantly reduce the post-surgical infection rate by 60% and reduce mortality.

In response to these and other findings, the US Surgical Infection Society ("SIS"), the Society for Hospital Epidemiologists of America ("SHEA"), the Infectious Disease Society of America ("IDSA") and the American Society of Hospital Pharmacists ("ASHP") published guidelines recommending that in the US all *Staphylococcus aureus* (including MRSA) carriers should be decolonised in all cardiovascular and most orthopaedic surgeries.

AHRQ/IDSA/SHEA recommended an even more aggressive treatment strategy, universal decolonisation (UD) of all Intensive Care Unit (ICU) patients without screening, awarding a Grade I (highest) level of evidence rating. US hospital groups, including the Hospital Corporation of America, are now implementing UD for all patients entering the ICU.

In Europe, similar guidelines exist recommending decolonisation of *Staphylococcus aureus* positive patients prior to certain surgeries.

The antibiotic mupirocin is often used off-label in the US for these applications, although it has two key disadvantages in that it is slow acting, requiring five days of dosing, and staphylococcal resistance to mupirocin can develop rapidly and become widespread. Consequently, many guidelines are accompanied with a resistance warning related to mupirocin use. In 2020 another new review concluded that global mupirocin-resistant *Staphylococcus aureus* prevalence had increased to 7.6% and that mupirocin-resistant MRSAs have increased by 13.8% and consequently the monitoring of mupirocin use remains critical.

Destiny Pharma believes this is clear support for the need for an alternative treatment for nasal decolonisation as presented by the XF-73 programme. (Ref. Mupirocin Resistance in *Staphylococcus aureus*: A Systematic Review and Meta-Analysis - Dadashi et al 2020).

**The commercial opportunity for XF-73 nasal is over a billion dollars**

There is a significant market for a new drug that can assist in the "prevention of post-surgical staphylococcal infections", particularly in the US. There are approximately 41 million surgeries per year in the US alone, all of which expose patients to the risk of post-surgical infections.

The market analysis undertaken by Destiny Pharma and its specialist consultants supports the view that XF-73 nasal could achieve annual peak sales in the US alone of over US$1 billion and peak sales in Europe and the rest of the world could be US$500 million for the initial indication of "prevention of post-surgical staphylococcal infections".

The most recent independent market reviews carried out in 2019 and 2022 updated the Company's understanding of current US and EU clinical practice, the competitor environment for the proposed XF-73 nasal gel formulation, pricing sensitivities and the payers' assessment of the target product profile ("TPP") of XF-73 nasal.

The study conclusions were very encouraging and reported that the sample of US/EU treaters (surgeons, infectious disease specialists and ICU specialists) and payers (hospital medical directors, pharmacy services directors, microbiologists and clinical directors) who were consulted confirmed that XF-73's target product profile is superior when compared to existing treatments.

This included off-label use of the antibiotic mupirocin in US, with the conclusion in both the US and EU being that XF-73 nasal has the potential to replace mupirocin as the preferred treatment. There was also strong support for a pricing strategy that could be at the higher end of previous assumptions.

**SPOR-COV COVID-19 programme**

The SPOR-COV prophylactic approach targets the innate immune system with the potential to develop COVID-19 protection within a few days of treatment. The 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 pre-clinical models of influenza.

SPOR-COV is different to vaccines in that it utilises the innate immune system with the aim of developing COVID-19 protection within 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 both high volumes and at low cost.

Additional attributes are that it can be stockpiled almost indefinitely without the need for cold chain refrigeration as it is a very stable product. 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.

In 2020, Destiny Pharma announced that Innovate UK ("IUK") awarded a grant of £800,000 to fund the majority of the £1 million cost of the initial SPOR-COV programme.

The pre-clinical efficacy work is being performed in collaboration with Professor Aras Kadioglu, at the University of Liverpool, who is Professor of Bacterial Pathogenesis in the Department of Clinical Infection, Microbiology & Immunology, where he heads the Bacterial Pathogenesis and Immunity group and is a leading expert in respiratory infection models and host immunity to infection.

The manufacturing and formulation development work will be carried out by HURO, an experienced manufacturer of bacterial product formulations based in Vietnam and part of PAN Group.

The plan is to complete the required pre-clinical safety and efficacy studies and also develop the manufacturing process by mid-2022, and be ready to commence the first human clinical studies thereafter. Further announcements will be made in H2 2022.

**Dermal programmes**

The Company is also running a XF-73 Dermal infection preclinical programme in collaboration with the expert National Institute of Allergy and Infectious Disease (NIAID) group in the US. A novel XF-73 Dermal formulation is being developed as a new treatment for serious wound infections such as those associated with diabetic foot ulcer infections (DFUs). This target market is estimated to be a US$500 million global sales opportunity 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. Driven by the growing number of diabetics and associated complications such as infected DFUs, this represents a significant market opportunity for XF-73.

China Medical System Holdings Limited (CMS), the Company's China regional partner and investor, has established its own differentiated dermal programme in 2021 with XF-73 targeting the prevention and treatment of superficial skin infections caused by bacteria.

As with all anti-infectives, AMR is also a concern within these dermal infection markets and the XF platform's "no/low resistance" profile is an additional benefit alongside the targeted product claims for efficacy and safety.

**Outlook for Destiny Pharma**

The strengthened balance sheet provides Destiny Pharma with working capital through to mid-2023, enabling us to complete the preparation of NTCD-M3 for our single Phase 3 study and be in a strong position to close a partnering deal. Following the positive Phase 2b clinical trial results for XF-73 nasal, Phase 3 design discussions are being held with regulators and when complete the Phase 3 study plans will then be added to our existing comprehensive data package and we will be in a good position to secure partners for XF-73 nasal.

Our cash resources are also being used to develop new dermal infection clinical candidates from the pre-clinical XF pipeline, contribute to our COVID-19 SPOR-COV project and to capitalise on commercial opportunities including additional grant funding, partnering, and licensing. Whilst the short-term focus is on our two valuable lead assets, Destiny Pharma will continue to establish research programmes through existing and new collaborations and, where possible, seek additional non-dilutive funding support as we have done successfully in the period under review.

Destiny Pharma has a great opportunity as a focused UK biotechnology company with full control of two high-quality, late-stage clinical assets targeted at infection prevention. Both are backed up by strong Phase 2 clinical data and have clear commercial positioning. The Board and employees are excited about the next stage in the Company's development and delivering on our strategy to build a world-leading infection prevention company.

**Neil Clark**
**Chief Executive Officer**
**12 April 2022**

**Chief Financial Officer's Statement**

**Financial review**
During 2021 we successfully completed our XF-73 nasal gel Phase 2b clinical study, announcing excellent data in Q2 2021. The focus for this programme is now on clarifying the European and US regulatory requirements for Phase 3 studies. Our other main

activity during the period was the commencement of the important manufacturing scale-up process for our NTCD-M3 programme, following the acquisition of this valuable asset at the end of 2020. Activity and associated investment in this programme will increase in 2022 as we ready the programme for commencement of a Phase 3 clinical study. Further progress was also made in our earlier programmes, in conjunction with our research partners, and we secured further collaborations for our dermal programme during the period. We increased headcount during the year to support our growth plans and also increased investment in our business development activities, including the appointment of a Chief Business Officer to lead our partnering strategy.

Following the year end, in March 2022, we announced a fundraise of up to £7 million via a £6 million Placing and £1 million Open Offer. The fundraise was successfully approved by shareholders on 28 March, the final gross proceeds amounting to £6.5 million. Proceeds will be utilised to advance our key programmes and strengthen the Company's balance sheet as we progress ongoing partner discussions. This is a significant achievement against the backdrop of very difficult market conditions, inflationary and interest rate headwinds and the geo-political events centred on Ukraine. We are very pleased to have received support from both existing and new investors at a critical time for the Company as we advance our two lead assets towards the commencement of Phase 3 clinical studies and seek licencing partners.

**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 £0.1 million (2020: £0.01 million) during the period.

**Operating expenses**
Operating expenses, which exclude the share-based payment charge of £0.4 million (2020: £0.1 million) during the period, amounted to £6.0 million (2020: £6.4 million). Included within this total are R&D costs totalling £3.7 million (2020: £4.5 million) which were £0.8 million lower than the previous year. This was largely due to reduced activity in our XF-73 nasal gel programme following completion of Phase 2b patient recruitment in 2020 and successful data read out in Q2 2021.

Other operating costs increased by 21% to £2.3 million (2020: £1.9 million) as a result of an increase in employee costs following recruitment of additional staff during the first half of the year. General overheads, included within this total, remained flat at £1.1 million, reflecting our continued focus on minimising non-R&D spend.

**Loss on ordinary activities before tax**
Loss before tax for the year was £6.3 million (2020: £6.5 million).

**Taxation**
The Company received a repayment of £1.1 million in respect of the R&D tax credit claimed during the year ended 31 December 2020. The R&D tax credit receivable in the balance sheet of £0.9 million is an estimate of the cash repayment the Company expects to qualify for in respect of activities during the year ended 31 December 2021. 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 8.9 pence (2020: 12.0 pence).

**Cash flow**
Net cash outflow from operating activities in 2021 was £5.1 million (2020: £5.5 million) against an operating loss of £6.3 million (2020: £6.5 million), with the major reconciling items being the non-cash charge for share-based payments of £0.4 million, the R&D credit received of £1.1 million and other net movements in working capital of £(0.3) million.

**Balance sheet**
Total assets decreased to £8.3 million (2020: £13.7 million) largely due to the utilisation of cash in the operating activities highlighted above.

Intangible assets solely comprise the initial acquisition cost of NTCD-M3, acquired in November 2020. Trade, other receivables, and prepayments decreased to £1.3 million (2020: £1.7 million) which was primarily due to lower upfront payments to the Company's clinical research organisation and lower R&D tax credit compared to prior year.

Year-end cash and cash equivalents totalled £4.6 million (2020: £9.7 million). This does not include the proceeds of the fundraise which concluded post year end.

Total liabilities decreased to £0.8 million (2020: £1.3 million) primarily due to timing of payment to trade creditors.

**Outlook**
During the next financial year, the Company will continue to invest in progressing its lead assets towards the commencement of Phase 3 clinical studies and developing its early-stage pipeline. The Company also remains focused on maintaining a disciplined cost base, seeking to minimise spend on non-core R&D activities. The successful fundraise in March 2022 provides the Company with a strong balance sheet as it seeks partners to co-fund required Phase 3 studies and lead commercialisation of its lead assets.

**Shaun Claydon**
**Chief Financial Officer**
**12 April 2022**

**Statement of comprehensive income**
For the year ended 31 December 2021

| | Notes | **Year ended 31 December 2021 £** | Year ended 31 December 2020 £ |
|---|---|---|---|
| **Continuing operations** | | | |
| Other operating income | 4 | **135,028** | 12,450 |
| Administrative expenses | | **(6,016,128)** | (6,425,471) |
| Share-based payment expense | | **(405,851)** | (139,491) |
| **Loss from operations** | | **(6,286,951)** | (6,552,512) |
| Finance income | 5 | **15,520** | 71,611 |
| **Loss before tax** | | **(6,271,431)** | (6,480,901) |

| | | | |
|---|---|---|---|
| Taxation | 6 | **931,951** | 1,069,824 |
| **Loss and total comprehensive loss for the year from continuing operations** | | **(5,339,480)** | (5,411,077) |
| **Loss per share - pence** | | | |
| Basic | 7 | **(8.9)p** | (12.0)p |
| Diluted | 7 | **(8.9)p** | (12.0)p |

**Statement of financial position**
As at 31 December 2021

| | Notes | **As at 31 December 2021 £** | As at 31 December 2020 £ |
|---|---|---|---|
| **Assets** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | | **35,882** | 18,141 |
| Intangible assets | 8 | **2,261,435** | 2,261,435 |
| **Non-current assets** | | **2,297,317** | 2,279,576 |
| **Current assets** | | | |
| Trade and other receivables | 9 | **991,913** | 1,172,403 |
| Cash and cash equivalents | 10 | **4,645,562** | 9,744,217 |
| Prepayments | | **347,950** | 508,363 |
| **Current assets** | | **5,985,425** | 11,424,983 |
| **Total assets** | | **8,282,742** | 13,704,559 |
| **Equity and liabilities** | | | |
| **Equity** | | | |
| Share capital | 11 | **598,719** | 598,169 |
| Share premium | | **27,091,466** | 27,085,506 |
| Accumulated losses | | **(20,180,879)** | (15,247,250) |
| **Shareholders' equity** | | **7,509,306** | 12,436,425 |
| **Current liabilities** | | | |
| Trade and other payables | 12 | **773,436** | 1,268,134 |
| **Current liabilities** | | **773,436** | 1,268,134 |
| **Total equity and liabilities** | | **8,282,742** | 13,704,559 |

**Statement of changes in equity**
For the year ended 31 December 2021

| | Share capital £ | Share premium £ | Accumulated losses £ | Total £ |
|---|---|---|---|---|
| **1 December 2020** | 438,652 | 17,296,337 | (9,975,664) | 7,759,325 |
| **Comprehensive loss for the year** | | | | |
| Total comprehensive loss | - | - | (5,411,077) | (5,411,077) |
| **Total comprehensive loss for the year** | - | - | (5,411,077) | (5,411,077) |
| **Contributions by and distributions to owners** | | | | |
| Issue of share capital | 159,517 | 10,209,105 | - | 10,368,622 |

| | | | | |
|---|---|---|---|---|
| Costs of share issue | - | (419,936) | - | (419,936) |
| Share-based payment expense | - | - | 139,491 | 139,491 |
| **Total contributions by and distributions to owners** | 159,517 | 9,789,169 | 139,491 | 10,088,177 |
| **31 December 2020** | 598,169 | 27,085,506 | (15,247,250) | 12,436,425 |
| **Comprehensive loss for the year** | | | | |
| Total comprehensive loss | **-** | **-** | **(5,339,480)** | **(5,339,480)** |
| **Total comprehensive loss for the year** | **-** | **-** | **(5,339,480)** | **(5,339,480)** |
| **Contributions by and distributions to owners** | | | | |
| Issue of share capital | **550** | **5,960** | **-** | **6,510** |
| Share-based payment expense | **-** | **-** | **405,851** | **405,851** |
| **Total contributions by and distributions to owners** | **550** | **5,960** | **405,851** | **412,361** |
| **31 December 2021** | **598,719** | **27,091,466** | **(20,180,879)** | **7,509,306** |

**Statement of cash flows**
For the year ended 31 December 2021

| | **Year ended 31 December 2021 £** | Year ended 31 December 2020 £ |
|---|---|---|
| **Cash flows from operating activities** | | |
| Loss before income tax | **(6,271,431)** | (6,480,901) |
| Depreciation of property, plant and equipment | **12,518** | 16,881 |
| Share-based payment expense | **405,851** | 139,491 |
| Finance income | **(15,520)** | (71,611) |
| | **(5,868,582)** | (6,396,140) |
| (Decrease)/increase in trade and other receivables and prepayments | **198,336** | (379,293) |
| (Decrease)/increase in trade and other payables | **(494,698)** | 469,995 |
| **Cash used in operations** | **(6,164,944)** | (6,305,438) |
| Tax received | **1,074,519** | 813,250 |
| **Net cash used in operating activities** | **(5,090,425)** | (5,492,188) |
| **Cash flows from investing activities** | | |
| Purchase of property, plant and equipment | **(30,260)** | (2,099) |
| Purchase of intangible assets | **-** | (2,261,435) |
| Interest received | **15,520** | 71,611 |
| **Net cash outflow from investing activities** | **(14,740)** | (2,191,923) |
| **Cash flows from financing activities** | | |
| New shares issued net of issue costs | **6,510** | 9,948,686 |
| **Net cash inflow from financing activities** | **6,510** | 9,948,686 |
| **Net (decrease)/increase in cash and cash equivalents** | **(5,098,655)** | 2,264,575 |
| Cash and cash equivalents at the beginning of the year | **9,744,217** | 7,479,642 |
| **Cash and cash equivalents at the end of the year** | **4,645,562** | 9,744,217 |

**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 novel medicines that prevent serious infections.

**2. Basis of preparation**
The financial statements have been prepared in accordance with UK-adopted International Accounting Standards ("UK-IAS"). 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. 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***
Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2021 reporting periods and have not been early adopted by the Company. These standards are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

**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 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| Government grants received during the year | **129,149** | 12,450 |
| Government grants accrued at 31 December | **5,879** | - |
| | **135,028** | 12,450 |
| Included in trade and other receivables (note 9) | **5,879** | - |

**5. Net finance income**

| | **31 December 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| **Finance income** | | |
| Deposit account interest | **15,520** | 71,611 |

**6. Income tax**

| | **31 December 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| Research and development tax credits based on costs in the financial year | **(927,256)** | (1,069,824) |
| Utilisation of previously unrecognised tax credit | **(4,695)** | - |
| | **(931,951)** | (1,069,824) |

**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 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| Loss for the year attributable to shareholders | **(5,339,480)** | (5,411,077) |
| Weighted average number of shares [1] | **59,851,442** | 45,219,999 |

**Loss per share - pence**

| | | |
|---|---|---|
| - Basic and diluted | **(8.9)p** | (12.0)p |

(1) In March 2022 the Company raised gross proceeds of £6.5 million through an equity fundraise, in which a total of 12,909,007 new shares were issued and allotted. This transaction could have significantly changed the weighted average loss per share if it had occurred before the end of the reported period.

**8. Intangible assets**

| | Acquired development programmes £ |
|---|---|
| **Cost** | |
| At 1 January 2020 | - |
| Additions | 2,261,435 |
| At 31 December 2020 | 2,261,435 |
| Additions | - |
| **At 31 December 2021** | **2,261,435** |

In 2020, the Company acquired NTCD-M3, a development stage programme for preventing toxic strains of *C. difficile* proliferating in the colon after antibiotic treatment. The asset has not been amortised as the programme has not yet generated products available for commercial use.
The programme has been assessed for impairment. The Company considers the future development costs, the probability of successfully progressing to product approval and the likely commercial returns, among other factors. The result of this assessment did not indicate any impairment in the year.

The key sensitivity for all development programmes is the probability of successful completion of clinical trials in order to obtain regulatory approval for sale. Should trials be unsuccessful, the programme will be fully impaired.

**9. Trade and other receivables**

| | **31 December 2021** £ | 31 December 2020 £ |
|---|---|---|
| Other receivables | **64,657** | 102,579 |
| Research and development tax repayment | **927,256** | 1,069,824 |
| | **991,913** | 1,172,403 |

**10. Cash and cash equivalents**

| | **31 December 2021** £ | 31 December 2020 £ |
|---|---|---|
| Cash and bank balances | **4,645,562** | 9,744,217 |

**11. Share capital**

| Ordinary shares of £0.01 each | **31 December 2021 Number** | 31 December 2020 Number |
|---|---|---|
| **Authorised**[1] | **n/a** | n/a |
| **Allotted and fully paid** | | |
| At 1 January | **59,816,921** | 43,865,195 |
| Issued for cash during the year | **55,000** | 15,951,726 |
| **At 31 December** | **59,871,921** | 59,816,921 |

(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 2021** £ | 31 December 2020 £ |
|---|---|---|
| **Authorised** | **n/a** | n/a |

| | | |
|---|---|---|
| **Allotted and fully paid** | **598,719** | 598,169 |

| | **31 December 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| **Share premium account** | **27,091,466** | 27,085,506 |

55,000 ordinary shares were issued during the year at a premium of £5,960.

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

***Grants of options***
On 21 January 2021, 180,436 Employee LTIP 2020 options were granted to four employees at an exercise price of £0.01 per ordinary share. The fair value per option was £1.12.

On 17 December 2021, 425,000 Employee LTIP 2018 options were granted to eleven employees at an exercise price of £1.156 per ordinary share, the fair value per option was £0.69, and 610,085 performance targeted Employee LTIP 2020 options were granted to four employees at an exercise price of £0.01 per ordinary share, the fair value per option was £0.19.

***IFRS 2 valuation***
The estimated fair value of share options granted during the period without performance conditions has been calculated by applying a Black-Scholes option pricing model. The fair value of options with performance conditions has been estimated using Monte Carlo modelling. The weighted average exercise price of options granted in the period was £0.411 (2020: £0.111).
Measurement assumptions were as follows:

| | **2021** | **2021** | 2020 | 2020 |
|---|---|---|---|---|
| Share price | £1.065 | £1.065 - £1.130 | £0.665 | £0.400 - £0.665 |
| Exercise price | £0.01 | £0.01 - £1.156 | £0.01 | £0.01 - £0.65 |
| Expected volatility | 58% | 58% - 82% | 76% | 49% - 76% |
| Expected option life | 3 years | 10 years | 3 years | 10 years |
| Risk-free rate | 0.84% | 0.37% - 0.84% | 0.38% | 0.28% - 0.38% |
| Expected dividends | £nil | £nil | £nil | £nil |
| Model used | Monte Carlo | Black-Scholes | Monte Carlo | Black-Scholes |

Prior to the year ended 31 December 2020, historical volatility was measured using a composite basket of listed entities in similar operating environments, given the limited trading history of the Company following its IPO in 2017; with effect from the year ended 31 December 2020, historical volatility is measured using the Company's share price only.

The number and weighted average exercise prices of share options were as follows:

| | **31 December 2021** | | 31 December 2020 | |
|---|---|---|---|---|
| | **Number of options** | **Weighted average exercise price** | Number of options | Weighted average exercise price |
| Balance outstanding at beginning of the year | **9,090,846** | **£0.067** | 7,090,226 | £0.068 |
| Granted during year | **1,215,521** | **£0.411** | 2,150,620 | £0.111 |
| Exercised during year | **(55,000)** | **£0.118** | - | - |
| Cancelled during year | - | - | (150,000) | £0.765 |
| Lapsed during year | **(492,242)** | **£0.010** | - | - |
| **Options outstanding at end of the year** | **9,759,125** | **£0.112** | 9,090,846 | £0.067 |
| Options exercisable at the end of the year | **6,675,226** | **£0.054** | 6,555,226 | £0.056 |

The expense arising from share-based payment transactions recognised in the year was as follows:

| | **31 December 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |
| Share-based payment expense | **405,851** | 139,491 |

**12. Trade and other payables**

| | **31 December 2021** | 31 December 2020 |
|---|---|---|
| | **£** | £ |

| | | |
|---|---|---|
| Trade payables | **218,156** | 725,593 |
| Social security and other taxes | **82,075** | 49,015 |
| Accrued expenses | **453,815** | 485,261 |
| Pension contributions payable | **19,390** | 8,265 |
| | **773,436** | 1,268,134 |

**13. Statutory accounts**
The financial information set out above does not constitute the Company's statutory accounts for the years ended 31 December 2021 or 2020 but is derived from those accounts. Statutory accounts for 2020 have been delivered to the registrar of companies, and those for 2021 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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