



Audited results for year ended 31 December 2022

Released : April 13, 2023

RNS Number : 0386W
Destiny Pharma PLC
13 April 2023

Destiny Pharma plc

("Destiny Pharma" or "the Company")

Audited results for the year ended 31 December 2022

Exclusive North American partnering deal worth up to \$570m plus royalties secured for NTCL

Phase 3 development plans finalised for XF-73 nasal following scientific advice from FDA and

XF-73 dermal commenced clinically enabling safety study sponsored by US Government's N

New XF research projects initiated in cystic fibrosis and oral mucositis

Leadership strengthened with appointment of Chief Medical Officer and two Non-Executive Dir

Balance sheet strengthened through £7.3 million fundraise post period end

Brighton, United Kingdom - 13 April 2023 - Destiny Pharma plc (AIM: DEST), a clinical stage innova 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 2022.

Financial highlights

- Loss before tax of £7.7 million (2021: £6.3 million)
- R&D expenditure of £4.9 million (2021: £3.7 million)
- Other operating expenses (excluding share based payment charge) of £2.5 million (2021: £6.5 million gross proceeds from Q1 2022 equity fundraise)
- Year-end cash and cash equivalents of £4.9 million (2021: £4.6 million)
- Post period equity fundraise of £7.3 million (gross)
- Cash runway extended to H2 2024

Operational highlights

NTCD-M3 for prevention of C. difficile infection recurrence

- Continued progress made on preparations for the Phase 3 clinical trial of NTCD-M3, including manufacturing scale up and regulatory clarity on Phase 3 clinical development plans.
- Positive scientific advice received from European Medicines Agency ("EMA") on proposed study design.
- US and European market research confirms substantial market opportunity for NTCD-M3 potential also validated by Sebela partnering deal announced in March 2023.
- Results from US research support the use of NTCD-M3 following all commonly used antibiotic treatments.
- Positive new data published on the absence of toxic gene transfer to NTCD-M3 in the peer-reviewed journal, Public Library of Science One ("PLOS ONE").

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

- US Food and Drug Administration (FDA) has clarified Phase 3 and US registration pathway for XF-73 nasal gel for the prevention of post-surgical staphylococcal infections.
- EMA feedback on XF-73 nasal gel Phase 3 programme identifies a clear route through European approval as a novel hospital infection prevention product.
- Global Phase 3 study design finalised following discussions with regulators and key opinion leaders.
- External European market research reports show that XF-73 nasal gel is seen as a very promising alternative to mupirocin, the current standard of treatment, by both clinicians and payers. This suggests XF-73 has the potential to replace the current standard of treatment as the preferred surgical nasal decolonisation agent.
- Destiny's own market analysis, supported by independent, specialist market research, indicates the global peak sales for XF-73 nasal in the US and Europe could be over \$1 billion.
- Active partnering programme initiated and early discussions with potential partners commenced.

Earlier pipeline and research projects

- SPOR-COV™, our collaboration with SporeGen to develop a novel nasal spray to prevent respiratory infections, including COVID-19 and influenza, has completed grant funded research with next steps being discussed and publications planned.
- Positive results in XF-73 dermal safety study from ongoing agreement with US Government.
- Destiny's China partner, China Medical System Holdings Limited ("CMS"), is conducting pre-clinical work on their own XF-73 dermal programme.
- XF-73 shown to enhance the activity of two antibacterial drugs with the potential to develop treatments for lethal lung infections and infected diabetic foot ulcers caused by antimicrobial resistant bacteria.
- Secured funding from the Cystic Fibrosis Foundation for new XF research project.
- Initiated new XF research project targeted at oral mucositis.

Post period highlights

- Exclusive collaboration and co-development agreement for North American (US, Canada rights to NTCD-M3 signed with Sebela Pharmaceuticals® worth up to \$570 million plus no partnership with Sebela will finance the future clinical development and commercialisation NTCD-M3 in North America whilst the Company retains majority rights for Europe and Rest of the world. Initial collaboration work has commenced and is progressing well.
- Successful equity fund raise of £7.3 million (gross) to enable closing of Sebela partnership, strengthen balance sheet and continue to progress NTCD-M3 and XF-73 nasal toward Phase 3 clinical studies.
- Peer reviewed paper published in Microbiology Spectrum concludes that NTCD-M3 is able to effectively and fully colonise the gut following fidaxomicin administration, indicating that NTCD-M3 would be effective in patients receiving this antibiotic, as well as older antibiotics, such as rifamycin and metronidazole.
- Landmark XF-73 nasal Phase 2b clinical data published in the leading US peer reviewed journal, Infection Control & Hospital Epidemiology.

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

"Destiny Pharma has made good progress in 2022 and in the first quarter of 2023. We recently completed a major out-licensing deal for NTCD-M3 and successfully strengthened our balance sheet through a £7.3 million (gross) in March 2023 which was supported by new and existing investors. This has given us a cash runway to H2 2024 and removed the significant overhang of Phase 3 clinical development costs for NTCD-M3, whilst providing for potential milestone payments, as NTCD-M3 is commercialised, of up to \$570 million in royalties. Our priority now is to continue seeking additional partners for our two late stage clinical programmes to bring forward the earlier stage research projects. There is an urgent global need for new, innovative prevention medicines and Destiny Pharma believes that our targeted and diversified pipeline meets this need and has substantial commercial potential that will drive value generation in the future."

Webcast

Destiny Pharma will host a webcast presentation followed by a live Q&A session at 10:30 am on 26/04/2023, accessible via the Investor Meet Company platform.

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 Destiny Pharma plc.

For further information, please contact:

Destiny Pharma plc

Neil Clark, CEO

Shaun Claydon, CFO

+44 (0)1273 704 440

pressoffice@destinypharma.com

Optimum Strategic Communications

Mary Clark / Nick Bastin / Jonathan Edwards / Eleanor Cooper

+44 (0) 7931 5000 66

DestinyPharma@optimumcomms.com

finnCap Ltd (Nominated Advisor and Joint Broker)

Geoff Nash / George Dollemore, Corporate Finance

Alice Lane / Nigel Birks / Harriet Ward, ECM
+44 (0) 207 220 0500

Shore Capital (Joint Broker)
Daniel Bush / James Thomas / Lucy Bowden
+44 (0) 207 408 4090

MC Services AG
Anne Hennecke / Andreas Burckhardt
+49-211-529252-12

Stern IR - US
Janhavi Mohite
+1-212-362-1200
janhavi.mohite@sternir.com

About Destiny Pharma

Destiny Pharma is a clinical stage, innovative biotechnology company focused on the development of medicines that can prevent life-threatening infections. Its pipeline has novel microbiome-based biologics and XF drug clinical assets including NTCD-M3, a Phase 3 ready treatment for the prevention of *Clostridioides difficile* infection (CDI) recurrence which is the leading cause of hospital acquired infection in the community. NTCD-M3 is a novel oral capsule, which has completed a positive Phase 2 clinical trial targeting the prevention of staphylococcal hospital infections including MRSA. It is also co-developing SPOR-COV™, a novel, biotech product for the prevention of COVID-19 and other viral respiratory infections and has earlier grant funding for research projects.

For further information on the Company, please visit www.destinypharma.com

Forward looking statements

Certain information contained in this announcement, including any information as to the Group's strategy, 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", "anticipates", "projects", "expects", "intends", "aims", "plans", "predicts", "may", "will", "seeks", "could", "assumes", "positioned" or "should" or, in each case, their negative or other variations or comparable terms, 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 Group concerning, among other things, the Group's results of operations, financial condition, prospects, 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 that could cause actual results or trends to differ materially. Each forward-looking statement speaks only to the particular statement. By their nature, forward-looking statements involve risks and uncertainties, many of which 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 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

We have maintained our focus on infection prevention and all our pipeline projects have made good progress over the period under review. The late stage of our lead clinical assets and the diversification in our pipeline represent a low risk in our approach to drug development.

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.

M3 programme also brings the company into the exciting area of the human microbiome and bio fast-developing area of medical science and investigation for new therapies. We are very pleased to have announced in March 2023 our partnering deal for North American (US, Canada and Mexico) rights in NTCD-M3 Pharmaceuticals.

We believe that XF-73 nasal, our other late-stage programme and the lead drug candidate from our company has a target product profile that is very attractive to hospital infection experts. There are many million operations in the US alone where a new drug is needed to help prevent post-surgical infections. There have been several independent papers published in recent years from experts in the US, Europe and Asia highlighting the clinical need for XF-73 nasal and the market potential of such a preventative approach.

Our biotherapeutic programmes and the human microbiome

The microbiome represents a paradigm shift that affects every aspect of biomedicine: our gut bacteria, health, disease and drug responses throughout the body, and can themselves be a novel type of microbiome. The human microbiome therefore has the potential to be a major new therapeutic modality. We are very excited about the potential of NTCD-M3 and SPOR-COV™ as our biotherapeutic assets.

NTCD-M3 *Clostridioides difficile* programme

NTCD-M3 was developed by GI infection 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. NTCD-M3 has successfully completed Phase 1 and Phase 2b trials. The Phase 2b study demonstrated a favourable safety/toxicology profile and 95% prevention of CDI recurrence.

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 and it has also recently been out-licensed by the company to a major pharmaceuticals company who will carry out the required clinical development including Phase 3 studies and commercialisation in North America.

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 to 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 other strains of *C. difficile* proliferating in the colon after antibiotic treatment. NTCD-M3 temporarily colonises the 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 were very promising. The study was a double-blind, placebo-controlled trial, among 173 patients aged >18 years, who were diagnosed with CDI (either a first episode or first recurrence). The results were a strong, statistically significant data set showing the onset of colonisation which provided protection during the early post-treatment period, making NTCD-M3 a valuable 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 comparable 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 the Phase 3 design and certain manufacturing scale-up aspects. Recent FDA and EMA meetings confirmed that a single Phase 3 study is required as a randomised, double-blind, placebo-controlled trial.

It requires about 700 patients in 2:1 randomisation of active to placebo and the primary endpoint would be the rate of recurrence of CDI at eight weeks post-treatment in adult patients treated with antibiotics for a first episode of CDI.

The company has undertaken market research to assess the US market size for prevention of CDI. The only approved drug is Merck's Zinplava, which is expensive and reimbursed at a level that significantly inhibits its uptake. It is expected that NTCD-M3 could be priced at \$1,500, delivering estimated peak sales of c.\$200 million.

The market for Europe and the rest of the world is estimated by Destiny Pharma to be a similar size. Total sales per annum of c.\$0.5 billion could be achieved. There is also the potential for additional sales from multiple recurrences (prevention/multiple recurrence) that could double the global peak sales to c.\$1 billion per annum.

The extra costs of care in the US per CDI patient range from \$10,000 to \$20,000 and the CDI-attributable cost in the US alone was estimated in 2016 at \$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.

SPOR-COV™ COVID-19/influenza programme

The SPOR-COV™ prophylactic approach targets the innate immune system with the potential to prevent COVID-19 and influenza.

COVID-19 protection within a few days of treatment. The product consists of a proprietary formulation of bacteria that will be administered nasally as a spray. SPOR-COV™ has already been shown 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 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 particularly 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; it is a very stable product. It could be made available globally as a cost-effective measure in the event of 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 initial £1 million cost of the initial SPOR-COV™ programme. The pre-clinical efficacy work was performed at the University of Liverpool using their expertise in respiratory infection models and host immunity to inform manufacturing and formulation development work has been carried out by HURO, an experienced manufacturer of bacterial product formulations based in Vietnam and part of PAN Group.

The plan was 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. This was the intention; the partners are looking at next steps including seeking partners to help co-fund further work, and announcements will be made later in 2023.

Our XF platform

The XF platform has demonstrated that it is delivering several exciting research and clinical programmes on infection prevention with the potential to deliver clear cost savings to healthcare systems across the world whilst delivering safe, effective anti-infective treatments that also address the issue of AMR. The lead product from the XF platform is XF-73 nasal.

Clinical data underpinning the XF-73 nasal programme is strong

The positive Phase 2b results announced in 2021 confirmed the potential of XF-73 nasal gel. XF-73 (chloride) was awarded Qualified Infectious Disease Product ("QIDP") status by the FDA in 2015. With this 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 the product is approved.

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

The Phase 2b study was a multi-centre, randomised, placebo-controlled study of multiple application concentration of XF-73 nasal gel to assess the antimicrobial effect of XF-73 nasal gel on *Staphylococcus aureus* nasal carriage in patients scheduled for cardiac surgical procedures. The results were excellent and confirmed that XF-73 nasal delivers effective decolonisation of the nose before surgery. Phase 2 results were published in March 2023 in the US journal Infection Control & Hospital Epidemiology.

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

The medical need to combat surgical infections is significant

Patient carriage of *Staphylococcus aureus* strains, including MRSA, is recognised as a growing problem. 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 Healthcare Epidemiologists of America ("SHEA"), the Infectious Disease Society of America ("IDSA") and the 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 surgery.

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

In 2020, the Journal of the American Medical Association ("JAMA") published updated guidelines the surgeons to perform topical intranasal decolonisation prior to surgery with the highest recommendation.

This publication advocates improving recovery after surgery and the recommendation was clear therapy be applied universally to all cardiac surgical patients, not only *Staphylococcus aureus* carriers

This is clear support for the approach proposed by Destiny Pharma with XF-73 nasal gel.

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

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

The company has finalised the Phase 3 study designs for XF-73 nasal at the end of 2022 after seeking advice from the key regulators in the US and Europe. Destiny Pharma is now able to establish the site of the Phase 3 studies and has started a targeted partnering campaign with the aim of finding partners in 2023 if possible.

The agreed plan is to carry out two Phase 3 randomised, double-blind, placebo-controlled clinical trials undergoing two different surgical procedures. The planned studies could deliver a data set that would be preferred, broad label for XF-73 nasal gel, supporting its use in all major surgeries as a novel treatment for fast, effective nasal decolonisation. This is also a very large commercial opportunity. In summary, the studies are:

Study 1: Adult patients undergoing mastectomy with immediate reconstruction or use of tissue expansion post-surgical staphylococcal infections who have screened positive for *S. aureus* carriage.

Study 2: Adult patients undergoing emergency or expedited hip Hemiarthroplasty ("HA") surgery to fractures at risk of post-surgical staphylococcal infections who have screened positive for *S. aureus* carriage.

Studies could commence in 2024 with potential approval in 2027. Partners are being sought to help fund studies and lead commercialisation.

The commercial opportunity for XF-73 nasal is over \$1 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 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 \$1 billion and peak sales in Europe and the world could be \$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, pricing sensitivities and the payers' assessment of the target product profile ("TPP") of XF-73 nasal.

XF research programmes

During the period under review the company has continued to work on several university collaborative projects to understand the activity of the XF platform in selected infection models including the activity of XF compounds against bacteria and fungi embedded in biofilms. The company also entered new research projects testing XF compounds in models of oral mucositis and cystic fibrosis, the latter research project being supported by a funding grant from the Cystic Fibrosis Foundation. The continuing research work adds to the understanding of the XF platform mode of action and helps identify potential new opportunities to develop targeted research projects to new clinical development opportunities for the XF platform. The company will continue to seek grant and non-dilutive funding support for these earlier stage research projects as it has done with some success, having secured approximately £3.5 million in grant funding since the IPO in 2017.

Outlook for Destiny Pharma

The recently announced partnering deal for NTCD-M3 demonstrates that management are delivering on the company's strategy. The Board and management are now focused on delivering further deals in 2023 with regards to XF-73 nasal. The strengthened balance sheet following the March 2023 fundraising provides Destiny Pharma with working capital through to H2 2024, enabling us to complete our obligations and

manufacturing of NTCD-M3 clinical material for the clinical development work that will be carried out by our partner Sebela Pharmaceuticals. Following the positive XF-73 Phase 3 design discussions held with the partner in 2022, the company now has clarity on the Phase 3 programme for the US and Europe that adds to the strong data package. We are in a good position to find partners for XF-73 nasal and that is a key corporate objective for 2023.

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

Destiny Pharma has a great opportunity as a focused UK biotechnology company with two high-quality clinical assets targeted at infection prevention. Both are backed up by strong Phase 2 clinical data and a clear commercial positioning. The Board and employees are excited about the next stage in the development and delivering on our strategy to build a world-leading infection prevention pipeline and a very valuable company for our shareholders.

Neil Clark
Chief Executive Officer
13 April 2023

Chief Financial Officer's Statement

Financial Review

During 2022, we successfully clarified the US and EU Phase 3 clinical development plan for XF-73 nasal and commenced an active partnering campaign to secure a commercialisation partner for the XF-73 nasal in 2023. We also continued to invest in the important manufacturing scale-up process for our NTCD-M3 programme, required for Phase 3 clinical studies and product commercialisation. This scale-up process for delivery of clinical study material, is targeted to complete by the end of 2023. Further progress was made on our earlier programmes with two active dermal infection projects running in the US and China, completion of the SPOR-COV™ COVID-19 grant-funded collaboration, initiation of a new XF research project to investigate the potential of XF-73 nasal for the treatment of mucositis and an award from the Cystic Fibrosis Foundation to investigate the potential of XF-73 nasal treatment for cystic fibrosis patients infected with MRSA.

We took the opportunity to strengthen our balance sheet in the first quarter of the year, raising £6.5 million in proceeds from investors, enabling us to maintain momentum in our programmes whilst seeking commercial partners. We slightly increased headcount and welcomed a new Chief Medical Officer during the year.

Following the year end, in February 2023, we announced an exclusive collaboration and co-agreement for North American rights for NTCD-M3 with Sebela Pharmaceuticals, a key milestone for the company. A condition of the Sebela transaction was the strengthening of the company's balance sheet. In connection with the transaction, we announced a fundraising of up to £8 million via a £7 million Placing and £1 million Open Offer at the same time. The fundraising was successfully approved by shareholders on 16 March 2023, the final gross proceeds were £7.3 million. Proceeds will be utilised in advancing our key programmes and strengthening the company's balance sheet as we intensify partnering activities, particularly for XF-73 nasal. The fundraising was achieved against a backdrop of challenging market conditions and we are very pleased to have received support from existing and new investors.

Revenue

Destiny Pharma is a clinical stage research and development company and is yet to commercialise any products or generate sales from its current programmes. The company received grant income of £0.2 million (2021: £0.1 million) in the period.

Operating expenses

Operating expenses, which exclude the share-based payment charge of £0.5 million (2021: £0.4 million), amounted to £7.4 million (2021: £6.0 million). Included within this total are R&D costs totalling £3.7 million (2021: £3.7 million) which were £1.2 million higher than prior year. This was largely due to increased costs in the NTCD-M3 programme as we progressed the manufacturing scale-up process and clinical and regulatory preparation for commencement of Phase 3 clinical studies.

Other operating costs increased 6% to £2.5 million (2021: £2.3 million). Other operating costs are comprised of general overheads, which remained flat at £1.1 million (2021: £1.1 million) and employee costs, which increased by £0.2 million to £1.4 million (2021: £1.2 million).

Loss on ordinary activities before tax

Loss before tax for the year was £7.7 million (2021: £6.3 million).

Taxation

The company received a repayment of £0.9 million in respect of the R&D tax credit claimed during the year ended 31 December 2021. The R&D tax credit receivable in the balance sheet of £1.2 million is an estimate of the repayment the company expects to qualify for in respect of activities during the year ended 31 December 2022. 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 9.3 pence (2021: 8.9 pence).

Cash flow

Net cash outflow from operating activities in 2022 was £5.9 million (2021: £5.1 million) against an operating profit of £7.8 million (2021: £6.3 million), with the major reconciling items being the non-cash charge for depreciation of £0.5 million, the R&D credit received of £0.9 million, grant income of £0.1 million and movements in working capital of £0.4 million.

Net cash from financing activities during the year of £6.1 million represents the net proceeds of a fundraising event in March 2022 (2021: £nil). The net increase in cash and cash equivalents during the year was £0.2 million (2021: decrease of £5.1 million).

Balance sheet

Total assets increased to £8.8 million (2021: £8.3 million) largely due to a higher R&D tax credit claim and a higher balance of cash and cash equivalents compared to prior year.

Intangible assets solely comprise the initial acquisition cost of NTCD-M3, acquired in November 2021, and prepayments increased to £1.6 million (2021: £1.3 million) which was primarily due to the R&D tax credit compared to prior year.

Year-end cash and cash equivalents totalled £4.9 million (2021: £4.6 million). This figure does not include the proceeds of the fundraising event nor the upfront receipt under the NTCD-M3 partnering deal, both of which are expected to be received in the year post year end.

Total liabilities increased to £1.2 million (2021: £0.8 million) primarily due to accrued development costs in relation to the NTCD-M3 programme.

Outlook

During the next financial year, the company will focus on completing the manufacturing scale-up to develop clinical trial material for the NTCD-M3 clinical programme being run by our partner Sebela, continue to progress development of XF-73 nasal toward commencement of Phase 3 clinical studies and develop its early stage pipeline. The company will remain focused on maintaining a disciplined cost base, seeking to minimise spend on non-core R&D activities. The successful partnering of NTCD-M3 and fundraising in March 2023 provides the company with a strong financial sheet as it continues to progress its pipeline and actively secure a partner to co-fund required Phase 3 studies and lead commercialisation of XF-73 nasal.

Shaun Claydon
Chief Financial Officer
13 April 2023

Statement of comprehensive income

For the year ended 31 December 2022

	Year ended	Year ended
	31 December	31 December
	2022	2021
Notes	£	£
Continuing operations		
Other operating income	7	154,499

Administrative expenses		(7,397,014)	(6,
Share-based payment expense		(533,829)	(
Loss from operations		(7,776,344)	(6,
Finance income	5	64,800	
Loss before tax		(7,711,544)	(6,
Taxation	6	1,207,975	
Loss and total comprehensive loss for the year from continuing operations		(6,503,569)	(5,
Loss per share - pence			
Basic	8	(9.3)p	
Diluted	8	(9.3)p	
Statement of financial position			
As at 31 December 2022			
		As at	
		31 December	31 D
		2022	
	Notes	£	
Assets			
Non-current assets			
Property, plant and equipment		24,621	
Intangible assets	9	2,261,435	2
Non-current assets		2,286,056	2
Current assets			
Other receivables	10	1,410,452	
Prepayments		195,814	
Cash and cash equivalents	11	4,903,461	4
Current assets		6,509,727	5
Total assets		8,795,783	8
Equity and liabilities			
Equity			
Share capital	12	733,071	
Share premium		33,043,569	27
Accumulated losses		(26,150,619)	(20,
Shareholders' equity		7,626,021	7

Current liabilities				
Trade and other payables	13	1,169,762		
Current liabilities		1,169,762		
Total equity and liabilities		8,795,783		8
Statement of changes in equity				
For the year ended 31 December 2022				
	Share capital £	Share premium £	Accumulated losses £	
1 January 2021	598,169	27,085,506	(15,247,250)	12
Comprehensive loss for the year				
Total comprehensive loss	-	-	(5,339,480)	(5,
Total comprehensive loss for the year	-	-	(5,339,480)	(5,
Contributions by and distributions to owners				
Issue of share capital	550	5,960	-	
Share-based payment expense	-	-	405,851	
Total contributions by and distributions to owners	550	5,960	405,851	
31 December 2021	598,719	27,091,466	(20,180,879)	7
Comprehensive loss for the year				
Total comprehensive loss	-	-	(6,503,569)	(6,
Total comprehensive loss for the year	-	-	(6,503,569)	(6,
Contributions by and distributions to owners				
Issue of share capital	134,352	6,332,565	-	6
Costs of share issue	-	(380,462)	-	(
Share-based payment expense	-	-	533,829	
Total contributions by and distributions to owners	134,352	5,952,103	533,829	6
31 December 2022	733,071	33,043,569	(26,150,619)	7

Statement of cash flows

For the year ended 31 December 2022

	Year ended 31 December 2022 £	Year e 31 Dece
Cash flows from operating activities		
Loss before income tax	(7,711,544)	(6,271
Depreciation of property, plant and equipment	12,328	12
Share-based payment expense	533,829	405
Finance income	(64,800)	(15
	(7,230,187)	(5,868
Decrease in other receivables and prepayments	14,316	198
Increase/(decrease) in trade and other payables	396,326	(494
Cash used in operations	(6,819,545)	(6,164
Tax received	927,256	1,074
Net cash used in operating activities	(5,892,289)	(5,090
Cash flows from investing activities		
Purchase of property, plant and equipment	(1,067)	(30
Interest received	64,800	15
Net cash inflow/(outflow) from investing activities	63,733	(14
Cash flows from financing activities		
New shares issued net of issue costs	6,086,455	6
Net cash inflow from financing activities	6,086,455	6
Net increase/(decrease) in cash and cash equivalents	257,899	(5,098
Cash and cash equivalents at the beginning of the year	4,645,562	9,744
Cash and cash equivalents at the end of the year	4,903,461	4,645

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 0316. 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 infection.

2. Basis of preparation

The financial statements have been prepared in accordance with UK-adopted International Accounting Standards. The financial statements have been prepared under the historical cost convention except where stated otherwise within the accounting policies.

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

3. Standards and interpretations issued

Certain new accounting standards and interpretations have been published that are not mandatory for 31 December 2022 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 future reporting periods and on foreseeable future transactions.

4. Segment reporting

The chief operating decision-maker is considered to be the Board of Directors of the company. The chief operating decision-maker monitors the 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.

5. Net finance income

	31 December 2022	31 December 2021
	£	£
Finance income		
Deposit account interest	64,800	1,000

6. Income tax

	31 December 2022	31 December 2021
	£	£
Research and development tax credits based on costs in the financial year	(1,207,975)	(1,207,975)
Utilisation of previously unrecognised tax credit	-	-
	(1,207,975)	(1,207,975)

7. Other operating income

	31 December 2022	31 December 2021
	£	£
Government grants received during the year	22,864	131,635
Government grants accrued at 31 December	131,635	-

	154,499	
Included in other receivables (note 10)	131,635	

8. 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 and equity shareholders for the period. As the company made losses during the period, there are no dilutive potential ordinary shares, therefore basic and diluted loss per share are identical. The calculation is as follows:

	31 December	31 D
	2022	
	£	
Loss for the year attributable to shareholders	(6,503,569)	(5,
Weighted average number of shares ⁽¹⁾	70,182,231	59
Loss per share - pence		
- Basic and diluted	(9.3)p	

(1) In March 2023, the company raised gross proceeds of £7.3 million through an equity fundraise, in which a total of 20,961,961 new shares were issued and allotted. This transaction could have significantly changed the weighted average loss per share if it had occurred at the end of the reported period.

9. Intangible assets

	dev
	pro
Cost	
At 1 January 2021	2
Additions	
At 31 December 2021	2
Additions	
At 31 December 2022	2

In 2020, the company acquired NTCD-M3, a development stage programme for preventing toxic strains of *C. difficile* proliferation after antibiotic treatment. The asset has not been amortised as the programme has not yet generated products available for commercial sale.

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 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.

10. Other receivables

	31 December	31 D
	2022	
	£	

Other receivables	202,477	
Research and development tax repayment	1,207,975	
	1,410,452	

11. Cash and cash equivalents

	31 December 2022	31 D
	£	
Cash and bank balances	1,903,461	2
Call deposits	3,000,000	2
Cash and cash equivalents	4,903,461	4

12. Share capital

	31 December 2022	31 D
Ordinary shares of £0.01 each	Number	
Authorised⁽¹⁾	n/a	
Allotted and fully paid		
At 1 January	59,871,921	59
Issued for cash during the year	13,435,184	
At 31 December	73,307,105	59

(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 2022	31 D
	£	
Authorised	n/a	
Allotted and fully paid	733,071	

	31 December 2022	31 D
	£	
Share premium account	33,043,569	27

13,435,184 ordinary shares were issued during the year at a premium of £6,332,565. Costs of share issue charged to share premium account for the year were £380,462.

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

Grants of options

On 24 January 2022, 54,282 Employee LTIP 2020 options were granted to four employees at an exercise price of £0.01 per option. The fair value per option was £0.96.

On 6 June 2022, 190,000 Employee LTIP 2020 options were granted to one employee at an exercise price of £0.46 per option. The fair value per option was £0.27.

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

	31 December 2022		31 December 2021	
	Weighted			
	Number of	average	Number of	exercise price
	options	exercise price	options	exercise price
Balance outstanding at beginning of the year	9,759,125	£0.112	9,090,846	£0.112
Granted during year	244,282	£0.360	1,215,521	£0.360
Exercised during year	(526,177)	£0.024	(55,000)	£0.024
Lapsed during year	(609,000)	£0.248	(492,242)	£0.248
Options outstanding at end of the year	8,868,230	£0.115	9,759,125	£0.115
Options exercisable at the end of the year	5,800,049	£0.035	6,675,226	£0.035

The weighted average remaining contractual life of share options outstanding at 31 December 2022 was 4.3 years (2021: 4.9 years).

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

	31 December 2022	31 December 2021
	£	£
Share-based payment expense	533,829	533,829

13. Trade and other payables

	31 December 2022	31 December 2021
	£	£
Trade payables	172,543	172,543
Social security and other taxes	80,369	80,369
Accrued expenses	898,326	898,326
Pension contributions payable	18,524	18,524
	1,169,762	1,169,762

14. Statutory accounts

The financial information set out above does not constitute the Company's statutory accounts for the years ended 31 December 2022 but is derived from those accounts. Statutory accounts for 2021 have been delivered to the registrar of companies, and those for 2022 will be delivered in due course. The auditor has reported on those accounts; their reports (i) were unqualified, (ii) did not include a statement of opinion on the financial statements, and (iii) did not contain a statement of opinion on the financial statements.

498 (2) or (3) of the Companies Act 2006.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

FR KLLFFXZLBBBZ