Destiny Pharma plc

AGM statement and recent progress

13 June 2024

Destiny's AGM included clinical and business development updates which we summarise below. In addition, there has been an increasing tempo in broader market news that helps augment Destiny's investment proposition. These include the UK government and GSK's pledge on antimicrobial resistance, plus the acquisition of rights to a competitor product to NTCD-M3 which we have always regarded as inferior to Destiny's NTCD-M3.

Encouragingly, there has also been the recent award of the Innovation Passport Designation (IPD) for Destiny's XF-73 Nasal.

AGM results and XF-73 Nasal titbits

All resolutions were passed in Destiny's 2024 AGM. In addition, there were important updates on Destiny's XF-73 Nasal product which we explore further in the body of the note. Destiny's CMO detailed the revised clinical program for XF-73 Nasal and what struck us most was the expected £25m cost. This was the average estimate from six or seven contract clinical research organisations. To most potential licensors of XF-73 Nasal, **this level of cost (and any upfront payments) would be a 'steal'** for a license that gets them to the other side of Phase 3, the rights to XF-73 Nasal in some jurisdictions, and a pathway to a regulatory submission.

During the Q&A, Destiny's CEO helpfully clarified that the ongoing review of strategic options – where an update will be provided to the market in a matter of weeks – is specifically **in respect of XF-73 Nasal,** rather than for Destiny Pharma itself.

XF-73 Nasal IPD

In a recent, well-received announcement, Destiny disclosed that its product XF-73 for the prevention of post-surgical staphylococcal infections had been awarded an IPD that provides entry into the UK's Innovative Licensing and Access pathway (ILAP). Like the similar award to Destiny by the US FDA of Qualifying Infectious Disease Product (QIDP) status, apart from the endorsement now by two transatlantic regulators, access to the ILAP provides **a number of tangible benefits** which we cover in more detail later in this note.

Valuation unchanged

Our fair value for Destiny Pharma plc remains at **£212.0m (or 234p / share)** since our recent changes that reflected the longer times until Phase 3 studies start and revenues flow back to Destiny. Ironically the recent IPD award may shorten some of these timelines, while QIDP status extends exclusivity, but we have not yet incorporated these positives into our valuation.

Summary Financials

£'000s, y/e 31 December	2020A	2021A	2022A	2023A	2024E
Revenues				832	
EBIT	-6,553	-6,287	-7,776	-6.736	-6,578
Basic EPS (p)	-12.0	-8.9	-9.3	-6.2	-6.0
Net Assets	12,436	7,509	7,626	9,189	4,480
Net Cash	9,744	4,646	4,903	6,383	2,250

Source: Company historic data, ED estimates.

Company Data

EPIC	DEST
Price (last close)	11.75p
52 weeks Hi/Lo	84p / 11p
Market cap	£11.2m
ED Fair Value Per share	£212m 234p
Reported cash end H2 23	£6.4m
Avg. daily volume	467k

Share Price, p

Source: ADVFN

Description

Destiny Pharma (Destiny) is an innovative clinical-stage biotechnology company focused on the development and commercialisation of novel medicines that can prevent life-threatening infections.

The company's drug development pipeline includes two late-stage assets, NTCD-M3, a microbiome-based biotherapeutic for the prevention of *C.difficile* infection (CDI) recurrence, which is the leading cause of hospital-acquired infection (HAI) in the US, and XF-73 nasal gel, a proprietary drug targeting the prevention of post-surgical staphylococcal infections including MRSA.

Destiny's shares are listed on AIM.

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Notes from the AGM

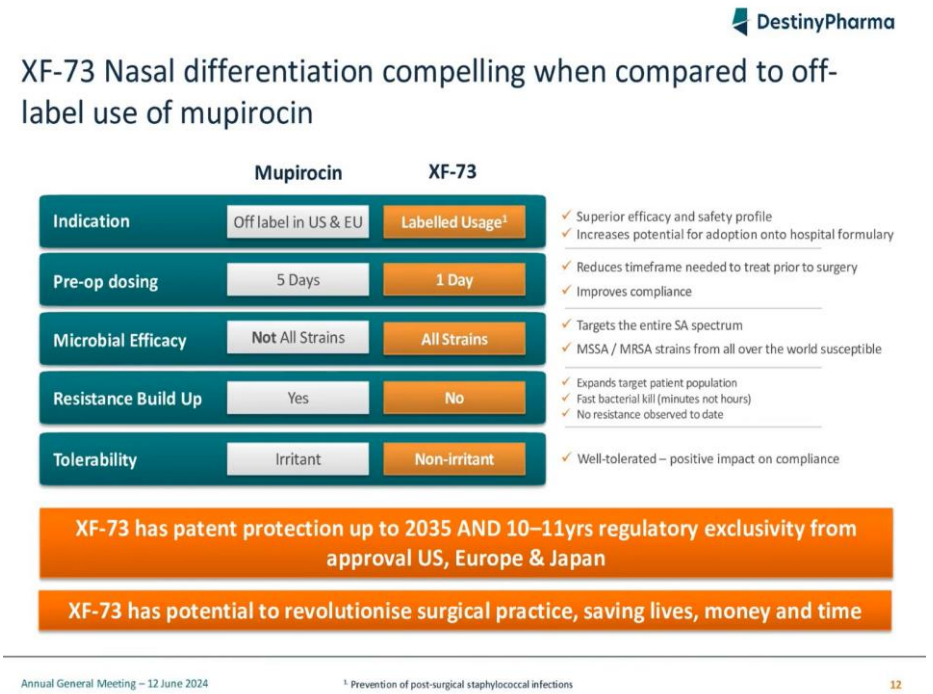
Once the formal shareholder aspects of the AGM were completed and all resolutions passed, Destiny's CEO and CMO gave presentations. The CEO's talk included a historical perspective on why anti-infective drug development had fallen out of favour. This has been true in the past and, while it is too early to suggest a renaissance, it is likely that the situation is reversing.

As Destiny's CEO pointed out, **XF-73 Nasal is an exception** to most of the factors that have muddied the investment case for antibiotic drug development. Furthermore, the UK government and GSK recently announced the **Flemming Initiative** to tackle antimicrobial resistance (AMR) with these first two founding partners committing £130m. This type of new initiative may help to spur on potential partners for XF-73 Nasal as they review the revised clinical plan and costings.

Destiny's CMO then summarised the **revised Phase 3 clinical program** which, besides being highly cost-effective, also achieves the same objectives of the former and larger program. It is likely that the previous program's cost caused some potential licensees to hesitate. It also struck us that Destiny has been able to retain a potentially broad label that includes breast reconstruction, cardiothoracic and orthopaedic surgeries, including those patients that are colonised by methicillin-resistant *Staphylococcus aureus* (MRSA).

In the past, antibiotic development programs have been criticised for excluding resistant strains (or at least not testing at sites during a MRSA outbreak, for example) but XF-73's broad anti-staphylococcal spectrum and activity against resistance and sensitive strains has probably given the company the confidence to rase this bar. The potential of XF-73 Nasal in the prevention of staphylococcal post-operative surgical infections *per se*, and its superior profile and advantages against the competition (mupirocin calcium nasal ointment) was well illustrated by this slide taken from Destiny's AGM presentation:

XF-73 Nasal differentiation



Source: Company AGM presentation

Ironically, when XF-73 Nasal is approved**, any emergence of resistance is unlikely** because in routine use, XF-73 Nasal would be self-administered prophylactically, probably without pre-screening for nasal colonisation. So, in about those two thirds of patients XF-73 Nasal would not be exposed to resistant nasal staphylococci. This preventative label and the significantly reduced potential for resistance generation (which in any case, has not yet been detected to XF-73 either in recent clinical isolates resistant to other antibiotics, or generated in the lab), should appeal to **both regulators** and **potential partners.**

Destiny's CMO described the revised Phase 3 program for XF-73 Nasal which, while it is designed to achieve the same outcomes as the previous version **at about £25m, costs significantly less** – another factor likely to appeal to potential partners. The CMO used the phrase "derisked' to describe the Phase 3 program's design and we have agreed with her view since before the Phase 2b study from the perspective of **XF-73 being a highly active anti-staphylococcal agent**.

Innovation Passport Designation (IPD)

Destiny's award of an IPD by the UK's regulator the MHRA is an important endorsement.

This highlights the acceptance of XF-73 Nasal's potential to address the unmet clinical need of staphylococcal post-operative surgical infections where the tempo of treatment failures due to antimicrobial resistance has been rising. Moreover, the current standard of care (mupirocin) is either not approved for this indication in the US or is typically reserved only for MRSA outbreak management in regions outside of the US.

Access to ILAP has multiple advantages and provides access to an early dialogue to drug regulators across the UK. Also of note, ILAP allows early access to the National Institute for Health and Care Excellence (NICE) which recommends whether drugs should be reimbursed in the National Health Service. This is important because so many times (US) biotech companies have submitted their health technology assessment forms to NICE with an outlandish sticker price and without any prior discussion, only to result in NICE's rejection. The early access and discussion via the IPD should help prevent that outcome for Destiny or its partners.

With one of the aims of the ILAP being to accelerate the time to market, the possibility remains that after a successful Phase 3 study XF-73 could be launched before our current model anticipates.

UPDATED FINANCIALS

Income Statement & Forecasts					
£'000s, y/e 31 December	2020A	2021A	2022A	2023A	2024E
IFRS Income Statement					
Total revenue				832	
Administration expenses	-1925	-2200	-2497	-3800	-2500
R&D	-4500	-3816	-4900	-3292	-3600
Other income (expense)		135	154		
Share-based payments & exceptionals	-139	-406	-534	-475	-475
Depreciation & amortisation				-2	-3
Reported EBIT	**-6553**	**-6287**	**-7776**	**-6736**	**-6578**
Reported profit before tax	**-6481**	**-6271**	**-7712**	**-6446**	**-6387**
Taxation	1070	932	1208	789	950
Reported Net income	**-5411**	**-5339**	**-6504**	**-5657**	**-5437**
Basic EPS (p)	-11.97	-8.92	-9.27	-6.24	-6.00
Diluted EPS (p)	-11.97	-8.92	-9.27	-6.24	-6.00

Source: Company historic data, ED estimates

Balance Sheet & Forecasts					
£'000s, at y/e 31 December	2020A	2021A	2022A	2023A	2024E
Assets					
Non-current assets					
Tangible assets	18	36	25	19	20
Intangible assets	2261	2261	2261	2341	2341
Total non-current assets	2280	2297	2286	2287	2287
Current assets					
Trade and other receivables	1172	992	1410	900	227
Cash and equivalents	9744	4646	4903	6383	2250*
Total current assets	11425	5985	6510	7597	2842
Total assets	13705	8283	8796	9957	5203
Equity and liabilities					
Equity					
Ordinary shares	598	599	733	953	953
Share Premium	27086	27091	33044	39569	39569
Retained earnings	-15247	-20181	-26151	-31332	-35041
Equity attributable to the company	12436	7509	7626	9189	4480
Total equity	12436	7509	7626	9189	4480
Current liabilities					
Trade and other payables	726	218	173	395	349
Total current liabilities	1268	773	1107	768	722
Total non-current liabilities					
Total equity and liabilities	13705	8283	8796	9957	5203

*Source: Company historic data, ED estimates. *including an estimated $1m milestone from XF-73 licensing transaction*

Cash Flow Statements & Forecasts

£'000s, y/e 31 December	2020A	2021A	2022A	2023E	2024E
Profit before taxation	-6481	-6271	-7712	-6446	-6387
Depreciation & amortisation	17	13	12	6	3
Share-based payments	139	406	534	475	475
Movements in working capital	91	-296	411	-428	
Net cash generated by operating activities	-5492	-5090	-5892	-5474	-5150
Investing activities					
CapEx on tangibles & intangibles	-2264	-30	-1	-81	-1
Acquisitions					
Other investing activities	72	16	65	290	191
Net cash used in investing activities	-2192	-15	64	209	191
Financing activities					
Proceeds from issue of shares	9949	7	6086	6745	
Movements in debt					
Net cash from financing activities	9949	7	6086	6745	826*
Cash & equivalents at beginning of year	7480	9744	4646	4903	2250
Cash & equivalents at end of year	**9744**	**4646**	**4903**	**6383**	**2250**

*Source: Company historic data, ED estimates. **Including an estimated $1m milestone from XF-73 licensing transaction.*

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