Destiny Pharma plc

Very welcome regulatory clarity

8 February 2022

Destiny Pharma has announced details of positive feedback from the European Medicines Agency (EMA) on the proposed Phase 3 programme for one of its two Phase 3-ready products, XF-73 for the prevention of post-surgical staphylococcal infections. Important implications can be emphasized from Destiny's announcement that should resonate with its potential partners. We explore these further in the body of this note.

EMA Scientific Advice

In the past, biotech companies would conduct clinical studies with very little reference or interaction with drug regulators until the submission of a new drug application. While many companies do still live in that regulatory bubble, fortunately Destiny Pharma is not one of them. For both Destiny's Phase 3-ready products, it has either had, or is in, discussions with the European (EMA) and US (FDA) regulators.

Destiny's most recent announcement reveals some details on the results of the discussions with the EMA: The first is that the successful completion of the proposed Phase 3 clinical programme is **expected to lead to the registration of XF-73 nasal gel in Europe**. While the number of patients in the study and the number of separate trials in the programme have not been disclosed, (probably for competitive reasons), any agreement (or scientific advice) with the European regulator should be viewed as **a positive step**. In addition, another typical mistake by smaller biotech companies is to make changes to a successful Phase 2 formula. In this respect, a similar microbiological endpoint of decolonisation, which resulted in the positive Phase 2b study reported last year, as well as the patient population – those at high risk of a post-surgical infection with *S.aureus* – have both been retained for Phase 3.

Furthermore, the protocol modifications developed for the Phase 2b study during the pandemic – which enriched for those patients colonised by *S.aureus*, will be retained in Phase 3. Unlike most clinical studies in the US where placebo-controlled studies are common, the EMA prefers active comparator studies and, in Destiny's case, Bactroban Nasal (mupirocin nasal formulation) will be the active control. This is likely to please infectious disease physicians because of mupirocin's association with antibiotic resistance (AMR).

Valuation and partnerships

We have left our valuation for Destiny Pharma unchanged but recognise that this announcement will enable potential partners to more easily value the costs of XF-73's European approval - and therefore makes a licensing transaction in FY 2022 more likely.

Our fair value of Destiny Pharma remains at £187.9m or 314p per share.

Summary Financials

£'000s, y/e 31 December	2017A	2018A	2019A	2020A	2021E
Revenues					
EBIT	-3,222	-6.084	-5,585	-6,553	-5,947
Basic EPS (p)	-8.5	-11.9	-10.8	-12.0	-8.6
Net Assets	16,686	12,257	7,759	12,436	7,893
Net Cash	16,724	12,061	7,480	9,744	5,329

Source: Company historic data, ED estimates.

Company Data

EPIC	DEST
Price (last close)	88p
52 weeks Hi/Lo	190p / 85p
Market cap	£53m
ED Fair Value - per share	£187.9m 314p
Net cash H1'21	£7.1m
Avg. daily volume	24,899

Share Price, p

Source: ADVFN

Description

Destiny Pharma (Destiny) is a clinical development-stage biotech company developing novel anti-infectives to prevent and treat infections caused by sensitive and resistant bacteria and viruses.

Destiny's proprietary drug discovery platform has generated a number of active antimicrobials including its lead drug XF-73. XF-73 has successfully completed a Phase 2b clinical study under a US IND for the prevention of staphylococcal post-operative infections. In September 2020, Destiny started a preclinical collaboration to prevent COVID-19 diseases by stimulating innate immunity. In November 2020, Destiny acquired the Phase 3-ready asset NTCD strain M3 for the prevention of *C.difficile* infections (CDI).

Destiny's shares are listed on AIM.

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Implications for XF-73

A microbiological primary endpoint, (like that used in Destiny's Phase 2b study), for its European Phase 3 programme, is **cheaper and quicker to measure, as well as less risky** than a hard clinical endpoint like the number of surgical infections. The EMA has clearly recognised the logic of both endpoints being correlated, and that the lower cost and speed to completion of studies are important advantages for European biotech companies.

In addition, the use of mupirocin as an active comparator could also result in a smaller study size because Bactroban Nasal has the wider nasal decolonisation label in Europe, so the study could be powered for non-inferiority. The non-inferiority to Bactroban Nasal in a European Phase 3 programme would be important since mupirocin-containing products are associated with the selection of bacterial resistance and treatment failure. The scientific advice of the EMA likely included input from infectious disease key opinion leaders who, while they value Bactroban Nasal for its utility in controlling methicillin-resistant *S.aureus* (MRSA) outbreaks (its only indication in the US), are concerned on its wider use and AMR generation in the prevention of high-risk surgical infections.

XF-73 has not been associated with AMR and, as such, is likely to be viewed as a logical replacement in both Europe and the US.

Another facet of Destiny's announcement was the agreement with the EMA on the patient population for the Phase 3 programme. This will be high-risk surgical patients (we have assumed segments of cardiovascular, orthopaedic and neurosurgical procedures where a *S.aureus* infection can have serious and costly implications), who are nasally colonised by *S.aureus*. Investors will remember that this enrichment of a broader all-comer high-risk surgical population was developed for the Phase 2b study during the pandemic to avoid recruiting and treating the two thirds of patients that are not colonised by *S.aureus*.

Carrying over this enrichment from Phase 2b to Phase 3 will also make the Phase 3 programme cheaper to conduct.

This matters to potential partners

The implications of a microbiological primary endpoint, non-inferiority to an active control and the recruitment of nasally colonised patients should be obvious cost advantages to Destiny's potential partners for XF-73.

The lower costs to achieve an approved product in Europe can therefore be quantified and make such a transaction more attractive to them than if Destiny had not put in all this effort.

Income Statement & Forecasts

£'000s, y/e 31 December	2017A	2018A	2019A	2020A	2021E
IFRS Income Statement					
Total revenue					
Administration expenses	-1011	-1800	-1887	-1925	-2100
R&D	-387	-3546	-3800	-4500	-3816
Other income (expense)	-613		306	12	
Share-base payments & exceptionals	-710	-738	-204	-139	-25
Depreciation & amortisation	-2	-4			-6
Reported EBIT	**-3222**	**-6084**	**-5585**	**-6553**	**-5947**
Reported profit before tax	**-3211**	**-6008**	**-5521**	**-6481**	**-5929**
Taxation	234	841	813	1070	800
Reported Net income	**-2977**	**-5167**	**-4708**	**-5411**	**-5129**
Basic EPS (p)	-8.45	-11.86	-10.75	-11.97	-8.58
Diluted EPS (p)	-8.45	-11.86	-10.75	-11.97	-8.58

Source: Company historic data, ED estimates

Balance Sheet & Forecasts

£'000s, at y/e 31 December	2017A	2018A	2019A	2020A	2021E
Assets					
Non-current assets					
Tangible assets	22	30	33	26	40
Intangible assets				2261	2261
Total non-current assets	22	30	33	2280	2301
Current assets					
Trade and other receivables	277	931	911	1172	547
Cash and equivalents	11724	7061	7480	9744	5329
Total current assets	17061	13028	8525	11425	6484
Total assets	17083	13058	8557	13705	8785
Equity and liabilities					
Equity					
Ordinary shares	436	436	439	598	598
Share Premium	17292	17292	17296	27086	27091
Retained earnings	-1042	-5471	-9976	-15247	-19796
Equity attributable to the company	16686	12257	7759	12436	7893
Total equity	16866	12257	7759	12436	7893
Current liabilities					
Trade and other payables	152	404	514	726	349
Total current liabilities	397	802	798	1268	892
Total non-current liabilities					
Total equity and liabilities	17083	13058	8557	13705	8785

Source: Company historic data, ED estimates

Cash Flow Statements & Forecasts

£'000s, y/e 31 December	2017A	2018A	2019A	2020A	2021E
Profit before taxation	-3211	-6008	-5521	-6481	-5929
Depreciation & amortisation	2	10	18	17	6
Share-based payments	710	738	204	139	211
Movements in working capital	165	381	-83	91	249
Net cash generated by operating activities	-2153	-4721	-4631	-5492	-4411
Investing activities					
CapEx on tangibles & intangibles	-23	-18	-21	-2264	-28
Other investing activities	-4990	76	5063	27	18
Net cash used in investing activities	-5013	58	5043	-2192	-10
Financing activities					
Proceeds from issue of shares	17406		7	9949	6
Movements in debt					
Net cash from financing activities	17409		7	9949	
Cash & equivalents at beginning of year	1481	11724	7061	7480	9744
Cash & equivalents at end of year	**11724**	**7061**	**7480**	**9744**	**5329**

Source: Company historic data, ED estimates

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