Destiny Pharma plc

Greater regulatory clarity given

19 July 2022

Destiny have announced an update on the discussions with the FDA on the Phase 3 development plans for XF-73 Nasal in the prevention of post-surgical staphylococcal infections. As one of Destiny's two Phase 3-ready products, the simplification of the Phase 3 study and its expected shorter duration brought about by XF-73's now accepted favourable safety profile will appeal to potential partners who should also appreciate the greater regulatory clarity. While we expect this announcement will improve the chances of a licensing transaction on XF-73 Nasal, we have maintained our valuation.

Positive FDA discussions

One of the aspects that potential licensees of XF-73 Nasal would need to know to value their return on the product is the ease of conducting the study, its cost, the comparator arm composition, and the duration of the Phase 3 program needed for approval. Destiny's announcement today goes a long way in providing its potential partners with comfort on these issues. The FDA has agreed to a Phase 3 study in nasally-colonised mastectomy patients. This patient population has a relatively high rate of post-surgical infection due to the source of infection being closer to the surgical wound, the lack of a systemic nasal decolonisation protocol, and chemo- and radiotherapy-induced immunosuppression. The number of US mastectomy surgeries is **nearly 16 times** our previous estimate of the number of US high-risk cardiovascular, neurosurgical, and orthopedic surgical procedures.

Welcome microbiological endpoint discussion

One of the major issues of running a study that measures the reduction in the number of infections is that infections in a closely monitored clinical trial setting where the standard of care is mandated by the protocol, are typically lower than in real-world settings. To address this, the FDA has agreed to the US Phase 3 study being conducted in mastectomy patients (with a higher number of patients to select from, recruitment is easier and, without ENT consultations or skin sensitivity tests, cheaper). The FDA also appears to be considering helping to establish the eradication of nasal carriage as a surrogate microbiological endpoint for the clinical endpoint of the reduction of the number of infections. Investors will remember that this microbiological endpoint was used in the successful Phase 2b study. Once a microbiological endpoint is correlated in one post-surgical infection indication, it could perhaps be used alone in other patient groups. For example, ones where the surgical sites may be further away from the nose but when an infection, although rare, can have significant morbidity, mortality, and cost implications. The Company is still targeting this wider patient population for the final TPP (target product profile) and use of XF-73 Nasal.

Valuation unchanged, for now

Regulatory clarity may make a XF-73 Nasal licensing transaction more likely. Our expectations for the timing of an XF-73 deal in FY 2023, and **our valuation remain at £209.6m or 288p per share.**

Summary Financials

£'000s, y/e 31 December	2018A	2019A	2020A	2021E	2022E
Revenues					
EBIT	-6,084	-5,585	-6,553	-6.287	-9,508
Basic EPS (p)	-11.9	-10.8	-12.0	-8.9	-11.9
Net Assets	12,257	7,759	12,436	7,509	3.957
Net Cash	12,061	7,480	9,744	4.646	1,185*

*Source: Company historic data, ED estimates. *Including illustrative debt simulating a $10m up licensing payment*

Company Data

EPIC	DEST
Price	36p
52 weeks Hi/Lo	130p / 35p
Market cap	£26.4m
ED Fair Value - per share	£209.6m 288p
Estimated net cash end FY 22	£1.2m
Avg. daily volume	28k

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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Income Statement & Forecasts

£'000s, y/e 31 December	2018A	2019A	2020A	2021A	2022E
IFRS Income Statement					
Total revenue					
Administration expenses	-1800	-1887	-1925	-2200	-2100
R&D	-3546	-3800	-4500	-3816	-6866
Other income (expense)		306	12	135	123
Share-base payments & exceptionals	-738	-204	-139	-406	-210
Depreciation & amortisation	-4				-2
Reported EBIT	**-6084**	**-5585**	**-6553**	**-6287**	**-9508**
Reported profit before tax	**-6008**	**-5521**	**-6481**	**-6271**	**-9457**
Taxation	841	813	932	800	800
Reported Net income	**-5167**	**-4708**	**-5411**	**-5339**	**-8657**
Basic EPS (p)	-11.86	-10.75	-11.97	-8.92	-11.90
Diluted EPS (p)	-11.86	-10.75	-11.97	-8.92	-11.90

Source: Company historic data, ED estimates

Balance Sheet & Forecasts

£'000s, at y/e 31 December	2018A	2019A	2020A	2021A	2022E
Assets					
Non-current assets					
Tangible assets	30	33	26	40	40
Intangible assets			2261	2297	2297
Total non-current assets	30	33	2280	2297	2338
Current assets					
Trade and other receivables	931	911	1172	992	992
Cash and equivalents	7061	7480	9744	4646	8597*
Total current assets	13028	8525	11425	5985	9877
Total assets	13058	8557	13705	8283	12215
Equity and liabilities					
Equity					
Ordinary shares	436	439	598	599	663
Share Premium	17292	17296	27086	27091	33692
Retained earnings	-5471	-9976	-15247	-20181	-30398
Equity attributable to the company	12257	7759	12436	7509	3957
Total equity	12257	7759	12436	7509	3957
Current liabilities					
Trade and other payables	404	514	726	218	349
Total current liabilities	802	798	1268	773	905
Total non-current liabilities					
Total equity and liabilities	13058	8557	13705	8283	12215

*Source: Company historic data, ED estimates, , * Illustrative debt representing a $10m upfront licensing transaction payment*

Cash Flow Statements & Forecasts

£'000s, y/e 31 December	2018A	2019A	2020A	2021E	2022E
Profit before taxation	-6008	-5521	-6481	-6271	-9457
Depreciation & amortisation	10	18	17	13	2
Share-based payments	738	204	139	406	210
Movements in working capital	381	-83	91	-296	0
Net cash generated by operating activities	-4721	-4631	-5492	-5090	-8496
Investing activities					
CapEx on tangibles & intangibles	-18	-21	-2264	-30	0
Other investing activities	76	5063	27	16	51
Net cash used in investing activities	58	5043	-2192	-15	-1420
Financing activities					
Proceeds from issue of shares		7	9949	7	6455
Movements in debt					7353*
Net cash from financing activities		7	9949	7	13807
Cash & equivalents at beginning of year	11724	7061	7480	9744	4646
Cash & equivalents at end of year	**7061**	**7480**	**9744**	**4646**	**1185***

Source: Company historic data, ED estimates.
**including $10m milestone and matching liability for $10m milestone*

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