Destiny Pharma plc

An educational R&D Day

19 October 2022

Destiny recently held a R&D Day and the presentations on its two Phase 3-ready products from key opinion leaders and Destiny's senior team effectively burnished the profile of the products, probably for the benefit of potential licensees. The schedule of hoped-for licensing transactions was laid out, with M3 targeted this year and XF-73 in 2023. Destiny also reiterated that Phase 3 studies will not start without the support of partners.

NTCD-M3: front and centre

Destiny's lead Phase 3-ready product is the non-toxigenic *Clostridioides difficile* strain M3 (NTCD-M3) for the prevention of *C.difficile* infections (CDI's). Professor Wilcox of Leeds University school of medicine outlined not just the **significant unmet medical need** of CDIs and the increasing incidence because of aging populations, but also a perspective on drug regulators and the competition to M3. In both the US and Europe, an unapproved competitor is the faecal microbiota transplantation (FMT).

In the US, while healthcare providers can claim a procedure cost (so might be incentivised to employ this undefined experimental therapy), the base case of drug regulators is to (in Prof. Wilcox's words) 'only give what is needed to help the patient' at the lowest effective dose. This is at odds with not just FMTs – which are undefined complex mixtures of millions of different faecal bacteria from volunteers – but by extension, the consortium mixtures of bacteria being developed by Destiny's competitors. Contrast these with M3 which is a single defined bacterial species that **does not need screening** for the expanding range of pathogens that are now required for FMTs and consortia products.

In addition, while companies like Seres Therapeutics are ahead of Destiny in completing their US regulatory submission, there must be concern at the FDA that the approval of a consortia product may suggest some legitimisation of unapproved FMTs and consortia. This is not an issue for a defined product like M3. Prof. Wilcox's presentation was supplemented by Destiny's current thinking on its Phase 3 trial design after discussion with regulators, and pharmacoeconomic costs for CDIs which again may have been for the benefit of Destiny's potential partners.

In the discussions on the data, the lower CDI recurrence rate of NTCD-M3 in Phase 2 and in animal models could have been due to its better fitness, rather than toxin-producing strains. This is because toxin production is a significant metabolic burden on pathogenic strains and the absence of this burden could allow M3 to out-compete toxigenic strains.

Valuation unchanged

Our valuation of Destiny's has not changed, despite continued US dollar strength (which impacts its upfront and milestone payments of a deal) nor in consideration of the larger breast reconstruction population for XF-73 (see later in this note).

We ascribe a fair value to Destiny Pharma of £251.2m or 345p per share.

Summary Financials

£'000s, y/e 31 December	2018A	2019A	2020A	2021A	2022E
Revenues					
EBIT	-6,084	-5,585	-6,553	-6.287	-7,008
Basic EPS (p)	-11.9	-10.8	-12.0	-8.9	-8.5
Net Assets	12,257	7,759	12,436	7,509	6.189
Net Cash	12,061	7,480	9,744	4.646	3,416*

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

Company Data

EPIC	DEST
Price	35.5p
52 weeks Hi/Lo	124p / 32p
Market cap	£26m
ED Fair Value - per share	£251.2m 345p
Reported cash end H1 22	£8.4m
Avg. daily volume	69k

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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XF-73's profile improves

Earlier in the year, Destiny's discussions with regulators resulted in a proposal for the Phase 3 study of XF-73 in the prevention of post-surgical staphylococcal infections to be conducted in breast reconstruction procedures in cancer patients. The presentation given by Dr Alex Mericli, a leading plastic surgeon at the MD Anderson Cancer Center in Texas, highlighted this **large and easily accessible market**. In addition, the significance of this unmet medical need is also due to the susceptibility of these patients to post-operative infections because of their prior immunosuppressive radiation therapy, amongst other factors.

Our valuation of the XF-73 component of Destiny Pharma has so far been in the much smaller number of high-risk cardiovascular, neurosurgery and orthopaedic surgery patients, albeit at a higher unit price. Although this market should not be excluded, before we approach the timeframe for an XF-73 licensing transaction in 2023, we shall revise our valuation of XF-73 to reflect its use in breast cancer reconstructive, and emergency fracture surgeries.

FINANCIALS

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	-4366
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**	**-7008**
Reported profit before tax	**-6008**	**-5521**	**-6481**	**-6271**	**-6957**
Taxation	841	813	932	800	800
Reported Net income	**-5167**	**-4708**	**-5411**	**-5339**	**-6157**
Basic EPS (p)	-11.86	-10.75	-11.97	-8.92	-8.46
Diluted EPS (p)	-11.86	-10.75	-11.97	-8.92	-8.46

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	12112*
Total current assets	13028	8525	11425	5985	13452
Total assets	13058	8557	13705	8283	15789
Equity and liabilities					
Equity					
Ordinary shares	436	439	598	599	663
Share Premium	17292	17296	27086	27091	33692
Retained earnings	-5471	-9976	-15247	-20181	-28166
Equity attributable to the company	12257	7759	12436	7509	6189
Total equity	12257	7759	12436	7509	6189
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	15789

*Source: Company historic data, ED estimates, * Illustrative debt re 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	-6957
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	-5996
Investing activities					
CapEx on tangibles & intangibles	-18	-21	-2264	-30	0
Acquisitions					-1739
Other investing activities	76	5063	27	16	51
Net cash used in investing activities	58	5043	-2192	-15	-1689
Financing activities					
Proceeds from issue of shares		7	9949	7	6455
Movements in debt					8696*
Net cash from financing activities		7	9949	7	15150
Cash & equivalents at beginning of year	11724	7061	7480	9744	4646
Cash & equivalents at end of year	**7061**	**7480**	**9744**	**4646**	**12112***

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

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