Destiny Pharma plc

Interim 2022 results: oodles of progress

8 September 2022

Destiny reported its H1 2022 financial results and provided an update on its pipeline progress. H1 R&D spend was below half our FY estimate but had increased on H1 2021. We have changed our forecasts and valuation to reflect both a lower spend than we had anticipated, and the $10m (now £8.7m) licensing transaction before YE 2022. Much of the regulatory work conducted in H1 2022 has increased the attraction of the profiles of NTCD-M3 and XF-73 at a time when Destiny's competitors are floundering. This is particularly true for NTCD-M3 where the EMA have approved just a single Phase 3 study.

H1 2022 Financials

Destiny's H1 2022 R&D expenses of £2.5m (*vs*. £2.0m in H1 2021) were lower than our £3.4m estimate of half the full-year spend so we have trimmed our estimated R&D expense for FY 2022. The increased R&D spend over H1 2021 was mainly due to the increased scale-up and regulatory costs on NTCD-M3. We now estimate a FY 2022 R&D expenditure of £4.4m. Administrative expenses appeared in-line with our estimates despite the higher pace of business development activity. The £609k in R&D tax credit (£489k in H1 2021) was higher than half our FY estimate of £400k and reflects the increased pace of R&D spend. These changes leave our estimates of Destiny's FY 2022 loss per share at 8.5p or £6.2m as Destiny continues to managed its finances prudently. Destiny's cash at the end of H1 2022 was £8.4m, (£7.1m at H1 2021), reflecting the recent fundraising and the lower H1 R&D spend than we had estimated, and provides a runway until at least mid-2023. Our YE 2022 estimate of cash is £12.1m, which includes our expectations of a c. $10m licensing transaction.

Burnishing the assets' profiles

Destiny's interim results summarise the developments on its pipeline, discussions with the regulators on its two Phase 3-ready assets, and what appears to be an accelerating pace of partnering activities: particularly on NTCD-M3. The attractiveness of these assets to licensing partners should have been increased by Destiny's efforts. The detailed regulatory discussions on the size, endpoints, and comparators of the Phase 3 studies of both NTCD-M3 and XF-73 will have taken most of the drug development 'heavy lifting' off a potential partner's shoulders – leaving them just to bring the money. In addition, while Destiny has been making progress, its competitors in the microbiome space seem to have been going backwards, which we explore further in the body of the note.

Valuation updated

The valuation has changed due to Destiny's lower near-term R&D spend and a stronger US dollar which impacts its upfront and milestone payments.

Our valuation of Destiny has risen: from £209.6m or 288p / share, to £251.2m or 345p / 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	38p
52 weeks Hi/Lo	127p / 35p
Market cap	£27.6m
Fair Value - per share	£251.2m 345p
Reported cash end H1 22	£8.4m
Avg. daily volume	59k

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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Significant progress

Destiny's interim results summarised what appears to have been **significant and detailed discussions** with both US and European regulators on its two Phase 3-ready assets: non-toxigenic *Clostridioides difficile* strain M3 (NTCD-M3) for *C.difficile* infections (CDIs) and the antimicrobial agent XF-73 for the prevention of post-operative staphylococcal infections.

NTCD-M3's profile has been improving in the last six months from a microbiome intervention that prevents the overgrowth of toxigenic strains in the colon after the disruptive effects of broad-spectrum antibiotic therapy, to a product that achieves that objective as well being associated with only the temporary colonisation of the colon and the restoration of normal bowel flora. Regulators in particular will appreciate the temporary nature of NTCD-M3's colonisation, but its longer-term beneficial effects on the gut microbiome. In addition, NTCD-M3's profile has been burnished ever further by the demonstration of its compatibility with another of the antibiotics used to treat CDI's and the inability for NTCD-M3 to either revert or acquire toxigenic potential

While much of the regulatory 'i's' and 't's' had been dotted and crossed on the regulatory requirements for the Phase 3 study of NTCD-M3 in CDIs, the interim statement's reiteration of **a single US study in 800 patients** should be a welcome reminder to potential partners. Destiny's interim statement also summarises the regulatory progress on XF-73 which brings it close to the regulatory position of NTCD-M3. Destiny have received feedback from both the FDA and EMA on their Phase 3 requirements for XF-73's approval and can now make that detail and the costings available to potential partners.

While a global Phase 3 programme for XF-73 is now possible, it is likely to include two studies – a placebo-controlled study in the US on top of the standard of care, and a comparator study in Europe where Bactroban Nasal (mupirocin calcium) is an approved product. Although an active comparator in Europe may be considered a higher bar, even for a microbiologically active product like XF-73, this is unlikely to be the case in the real world. This is because when the dermal ointment of Bactroban went over the counter in New Zealand, a high level of mupirocin resistance resulted and forced the product back to restricted prescription status. This is why the FDA only approved Bactroban Nasal in the very restricted indication of the eradication of nasal carriage of MRSA in an outbreak situation.

Unlike mupirocin, XF-73 has not been associated with the generation of resistant pathogens.

Competition flounders

While the profile of the single strain microbiome product NTCD-M3 has continued to improve in H1 2022, other microbiome competitors – that are complex consortia mixtures or even more complex donor-derived products – have not been so fortunate.

MaaT Pharma's donor-derived microbiome product for graft versus host disease remains on clinical hold by the FDA. As was Finch Therapeutics' consortium microbiome product for the prevention of CDIs before the clinical hold was removed in March 2022. But in an indication of the safety concerns that – unlike NTCD-M3 – hang over either donor-derived, or complex mixture consortia microbiome products, Finch's partner Takeda recently exited its collaboration on two microbiome products for gastrointestinal indications that was signed in 2017.

By contrast, Destiny believes that NTCD-M3 has clear advantages in the prevention of CDI recurrence as it is **a precise, non-toxic, single strain** that is targeted at stopping the effects of the dangerous toxic strains of CDI.

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 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	-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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