

## Validation for microbiomes

5 December 2022

With the first ever FDA approval for a faecal microbiome drug the door has been opened for other microbiome approaches to follow. Yet the profile of Ferring Pharmaceuticals' Rebyota leaves plenty of room for improvement by competitor products, such as Destiny's NTCD-M3. If nothing else, with Destiny's stated aim being a licensing deal for NTCD-M3, the FDA approval of Rebyota and the comparison with M3 should motivate its potential partners even more.

### Precedent set

After the FDA's approval of Ferring Pharma's Rebyota (fecal microbiota, live-jslm) the stage has been set for a **new era of microbiome drug approvals**. In many respects Rebyota has set a low bar for the competitor products that come after it, such as Destiny's non-toxicogenic *Clostridioides difficile* strain M3 (NTCD-M3). The bar has been lowered because: firstly, the FDA has signalled that it can approve microbiome drugs to treat *C.difficile* infections (CDIs). Secondly, the efficacy of Rebyota appears inferior to the Phase 2 data on NTCD-M3. Rebyota demonstrated a 70.6% absence of CDI diarrhoea compared to 57.5% with placebo, or a **13.1% difference in success over placebo**.

Different clinical trials are rarely comparable because Ferring measured treatment success (or non-recurrence) while the Phase 2 study of M3 measured CDI recurrence. However, in contrast to Rebyota, Destiny's NTCD-M3 demonstrated between a 11% and 5% CDI recurrence rate depending on the dose compared to a 30% recurrence rate with placebo, or a **19% to 25% difference over placebo**. If simplistically CDI recurrence = 1 – (CDI non-recurrence or success), then Destiny's M3 product's efficacy range in Phase 2 would have shown **89% to 95% treatment success**, *significantly better than Rebyota*.

### Plenty of scope to improve

Outside of clinical efficacy comparisons, M3 has a number of significant advantages over Rebyota. M3 is an orally administered capsule of  $10^7$  spores of the single strain NTCD-M3 in a dry powder stored at room temperature. Rebyota is between  $10^8$  and  $10^{10}$  different faecal bacteria species that are **thawed from frozen storage** for 24 hours before being administered **through a tube that is inserted 5 inches into the rectum**.

In addition, because Rebyota is isolated from volunteers, significant resources are needed to screen their faeces for pathogens that could be transmitted to patients before Rebyota is prepared and frozen – costs that when added to the freezing, storage, thawing, and administration costs **are likely to leave M3 with a significant cost of goods advantage**.

### Fair value unchanged

Our valuation remains unchanged: 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
<b>Revenues</b>					
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 (last close)	29.5p
52 weeks Hi/Lo	124p / 29p
Market cap	£21m
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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## FINANCIALS

Income Statement & Forecasts					
£'000s, y/e 31 December	2018A	2019A	2020A	2021A	2022E
<b>IFRS Income Statement</b>					
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
<b>Reported EBIT</b>	<b>-6084</b>	<b>-5585</b>	<b>-6553</b>	<b>-6287</b>	<b>-7008</b>
<b>Reported profit before tax</b>	<b>-6008</b>	<b>-5521</b>	<b>-6481</b>	<b>-6271</b>	<b>-6957</b>
Taxation	841	813	932	800	800
<b>Reported Net income</b>	<b>-5167</b>	<b>-4708</b>	<b>-5411</b>	<b>-5339</b>	<b>-6157</b>
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
<b>Assets</b>					
<b>Non-current assets</b>					
Tangible assets	30	33	26	40	40
Intangible assets			2261	2297	2297
Total non-current assets	30	33	2280	2297	2338
<b>Current assets</b>					
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
<b>Total assets</b>	<b>13058</b>	<b>8557</b>	<b>13705</b>	<b>8283</b>	<b>15789</b>
<b>Equity and liabilities</b>					
<b>Equity</b>					
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
<b>Current liabilities</b>					
Trade and other payables	404	514	726	218	349
Total current liabilities	802	798	1268	773	905
Total non-current liabilities					
<b>Total equity and liabilities</b>	<b>13058</b>	<b>8557</b>	<b>13705</b>	<b>8283</b>	<b>15789</b>

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	2021A	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
<b>Investing activities</b>					
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
<b>Financing activities</b>					
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
<b>Cash &amp; equivalents at end of year</b>	<b>7061</b>	<b>7480</b>	<b>9744</b>	<b>4646</b>	<b>12112*</b>

Source: Company historic data, ED estimates.

\*including estimated \$10m milestone and matching liability for \$10m milestone



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