Destiny Pharma plc

Interim results: XF-73 3–0 The competition

21st September 2023

There were few surprises in Destiny Pharma's interim results as the recent achievements on its two lead Phase 3-ready products had previously been announced. We have made minor changes to our forecasts but none to our valuation as a result of the interims. Destiny's new CEO delivered a polished and knowledgeable presentation only twelve days into the job handling analysts' questions with ease and delegating to Destiny's CFO and CSO where appropriate. We have delved into the details of the analysts' meeting in the body of this note.

H1 2023 Results

Destiny's H1 2023 R&D **expenses were lower than our expectations** because of the reduced spending and phasing of the costs on the M3 programme and lowered spend on earlier programmes. The £1.9m in H1 23 R&D spend was also lower than the £2.5m in H1 2022 because Destiny still had costs for the XF-73 Phase 2b clinical study. Administrative expenses of £2.0m (*vs.* £1.0m for H1 2022) were a touch higher than our expectations due to one-off board costs and the **investment in business development and market research**. The H1 2022 after-tax loss of £2.7m is therefore slightly higher than our expectations because of these one-off items, but there are still parts to move – like the R&D tax credit and the proceeds of an XF-73 transaction – that could easily offset this before Destiny's year-end. Nevertheless, we have adjusted slightly our FY 2023 R&D and Administration expense numbers to better reflect the interims. Destiny's cash position of £9.8m (*vs.* £8.4m at end H1 2022) is also modestly below our expectations due to the one-off H1 costs but like the H1 2023 loss, could easily reverse before the year-end. Destiny's **cash runway is expected to last at least until Q1 2025** after the recent fundraising of £6.7m net of costs.

Introducing Destiny's new CEO

We had time to talk with Destiny's new CEO, Chris Tovey and was impressed with his commercial and manufacturing background in pharmaceuticals and especially anti-infectives. This shone through in a polished and educational analysts' meeting presentation. From Destiny's perspective it is important to have someone who is well-versed in commercial pharmaceutical operations and who can easily convey the features and benefits of Destiny's pipeline products. Not only has Destiny found these facets in Chris, it also has someone who has **commercialised hospital-administered products**. Investors will remember that Destiny's two lead products NTCD-M3 and XF-73 will be administered mostly in hospital to prevent *Clostridioides difficile* infections (CDIs) and post-operative staphylococcal surgical infections, respectively.

Fair value unchanged

Our fair value for Destiny Pharma plc is unchanged at £254.7m (or 279 pence per share) after Destiny's interims.

Summary Financials

£'000s, y/e 31 December	2020A	2021A	2022A	2023E	2024E
Revenues					
EBIT	-6,553	-6,287	-7,776	-7,833	-6,353
Basic EPS (p)	-12.0	-8.9	-9.3	-7.4	-5.7
Net Assets	12,436	7,509	7,626	8,487	3,208
Net Cash	9,744	4,646	4,903	5,941	1,795

Source: Company historic data, ED estimates.

Company Data

EPIC	DEST
Price	54.0p
52 weeks Hi/Lo	62p / 25p
Market cap	£51.5m
ED Fair Value - per share	£254.7m 279p
Reported cash end H1 23	£9.8m
Avg. daily volume	463k

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).

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Notes from the analysts' meeting

As well as Destiny Pharma's H1 2022 results - which had few surprises – the interims were the first chance for analysts to meet and question its new CEO, twelve days into the job. Already Chris Tovey has reviewed and interrogated the chemistry, manufacturing and controls (CMC) components for the Phase 3 study of Destiny's lead product, the non-toxigenic *Clostridioides difficile* strain M3 (NTCD-M3). Not only this, but Chris has identified changes that are not material to the timeline that should assist not just the change in dosage form from the liquid to the solid capsule administration between Phase 2 and Phase 3, but the final commercial product manufacture. This illustrates the value of Chris' operational experience.

As well as all the other things a new CEO needs to do, Chris seems very focussed on the big items which are maintaining and enhancing the relationship with Sebela Pharmaceutical – the licensee of M3 for North America – and the requirements for its Phase 3 clinical programme, and not just in the US. The second big item on Chris' list is the licensing of XF-73 Nasal. Chris has already had his first meeting with Sebela's CEO. Destiny's publication strategy on M3, which includes the recent publication that demonstrated its effectiveness alongside the traditional antibiotics to treat CDI's – vancomycin, metronidazole and fidaxomicin – will aid the Sebella collaboration since fidaxomicin is largely a US market-only antibiotic.

Focus on XF-73

With the spotlight now on a licensing transaction for Destiny's second product XF-73, the recent publication of Destiny's positive Phase 2b study in a leading US peer reviewed journal and its scientific advisory board's confirmation of the proposed Phase 3 development pathway, also hint of Destiny's publication strategy's dovetailing with business development and partners should be reassured by these efforts. Destiny's recent survey of physicians and payers will also be relevant to potential licensees.

The discussion in the analysts' meeting included the agreement by the US FDA and European regulator on a single positive Phase 3 study for M3's approval. Destiny's previous statements have stated that this will be in breast reconstruction following mastectomy and expedited hip surgery patients. Our £88.6m risk-adjusted valuation of M3 is based on only on the smaller high-risk cardiovascular and orthopaedic surgical patients where we have forecasted peak sales (by Destiny's partner) at $2.2bn (in the US, EU, Japan and China). This differs slightly from Destiny's survey which underscores a $2bn market potential in the US alone. Also discussed was a potential second study for XF-73 which may correspond to our high-risk surgical patients. In any event, we have previously discussed the breast reconstruction indication as **an inspired choice** because of the ease of recruitment and therefore the likely strength of the post-operative infection signal, as well as the size of the market. Our valuation of XF-73 does not currently include this large market segment, but we will watch these developments with interest.

XF-73 dosing was also discussed with the **dosing advantages** of its three doses – one the day before surgery, one just prior and one just after the procedure – being much more attractive than that of Bactroban Nasal (mupirocin calcium) which is two to three times a day for five days. The less attractive dosing convenience of Bactroban Nasal often leads to compliance issues, and therefore reduced real world efficacy.

Another analyst asked about the pricing of generic mupirocin ointment complicating Destiny's premium pricing assumptions for XF-73 Nasal. Our forecasts, and we assume Destiny's pricing assumptions, are based on the US price of Bactroban Nasal, not branded or generic mupirocin dermal ointment. This is important because Bactroban Nasal was developed with a different salt of mupirocin and a different vehicle because the use of mupirocin ointment in the nose is associated with irritation which further reduces compliance and therefore efficacy. There is no generic mupirocin calcium product available so Destiny's and **our pricing assumptions with a premium to Bactroban Nasal are valid**.

An interesting, little-known fact about Bactroban Nasal is that when SmithKline Beecham filed its new drug application in the US, the proposed indication was the same as had been granted in Europe, the eradication of nasal *Staphylococcus aureus* carriage. However, the FDA was (and still is) so worried about the generation of mupirocin resistance that it restricted Bactroban Nasal only to the much smaller indication of the eradication of methicillin-resistant *S.aureus* as part of a hospital outbreak control program. XF-73 has no such resistance concerns and with the global sensitivities to antimicrobial resistance, the FDA probably regards its lack of resistance in clinical isolates as a valuable component of pre-operative nasal decolonisation and an **advantage compared to the competition**.

FINANCIALS

Income Statement & Forecasts

£'000s, y/e 31 December	2020A	2021A	2022A	2023E	2024E
IFRS Income Statement					
Total revenue					
Administration expenses	-1925	-2200	-2497	-3100	-2500
R&D	-4500	-3816	-4900	-4066	-3600
Other income (expense)		135	154		
Share-based payments & exceptionals	-139	-406	-534	-250	-250
Depreciation & amortisation				-2	-3
Reported EBIT	**-6553**	**-6287**	**-7776**	**-7833**	**-6353**
Reported profit before tax	**-6481**	**-6271**	**-7712**	**-7686**	**-6174**
Taxation	1070	932	1208	950	950
Reported Net income	**-5411**	**-5339**	**-6504**	**-6736**	**-5224**
Basic EPS (p)	-11.97	-8.92	-9.27	-7.38	-5.73
Diluted EPS (p)	-11.97	-8.92	-9.27	-7.38	-5.73

Source: Company historic data, ED estimates

Balance Sheet & Forecasts

£'000s, at y/e 31 December	2020A	2021A	2022A	2023E	2024E
Assets					
Non-current assets					
Tangible assets	18	36	25	25	26
Intangible assets	2261	2261	2261	2261	2261
Total non-current assets	2280	2297	2286	2287	2287
Current assets					
Trade and other receivables	1172	992	1410	1410	227
Cash and equivalents	9744	4646	4903	5941*	1795**
Total current assets	11425	5985	6501	7547	2268
Total assets	13705	8283	8796	9834	4555
Equity and liabilities					
Equity					
Ordinary shares	598	599	733	943	943
Share Premium	27086	27091	33044	39431	39431
Retained earnings	-15247	-20181	-26151	-31887	-37166
Equity attributable to the company	12436	7509	7626	8487	3208
Total equity	12436	7509	7626	8487	3208
Current liabilities					
Trade and other payables	726	218	173	349	349
Total current liabilities	1268	773	1107	1347	1347
Total non-current liabilities					
Total equity and liabilities	13705	8283	8796	9834	4555

*Source: Company historic data, ED estimates. *Including $1m upfront milestone from M3 licensing transaction. **including an estimated $1m milestone from XF-73 licensing transaction*

Cash Flow Statements & Forecasts

£'000s, y/e 31 December	2020A	2021A	2022A	2023E	2024E
Profit before taxation	-6481	-6271	-7712	-7686	-6174
Depreciation & amortisation	17	13	12	2	3
Share-based payments	139	406	534	250	250
Movements in working capital	91	-296	411		
Net cash generated by operating activities	-5492	-5090	-5892	-6631	-5150
Investing activities					
CapEx on tangibles & intangibles	-2264	-30	-1		-1
Acquisitions					
Other investing activities	72	16	65	147	178
Net cash used in investing activities	-2192	-15	64	147	178
Financing activities					
Proceeds from issue of shares	9949	7	6086	6737	
Movements in debt					
Net cash from financing activities	9949	7	6086	7522*	826**
Cash & equivalents at beginning of year	7480	9744	4646	4903	5941
Cash & equivalents at end of year	**9744**	**4646**	**4903**	**5941**	**1795**

*Source: Company historic data, ED estimates. *Including $1m upfront milestone from M3 licensing transaction. **Including an estimated $1m milestone from XF-73 licensing transaction.*

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