Destiny Pharma plc

NTCD-M3 competitors stumble while issue approved

29 March 2022

With the recently announced fundraising approved at Destiny's GM, and the competition to Destiny's Phase 3-ready NTCD-M3 product flailing, everything seems to be in place for a partnering transaction. Destiny has successfully raised £6.45m in a Placing, Subscription, and Open Offer which, apart from funding the further preparation of its two lead assets for the Phase 3 studies, puts Destiny in a stronger position in licensing negotiations. Our valuation has changed as a result of the fundraising.

Fundraising approved

All resolutions relating to the placing, subscription and open offer have now been approved by shareholders and Destiny **has successfully raised £6.45m gross,** which is now included in our financials (and valuation) below, net of our (7%) estimate of costs. Business development activities have almost certainly been ongoing since the licensing of the non-toxigenic *Clostridioides difficile* strain M3 (NTCD-M3) product for the treatment of *C.difficile* infections (CDIs), and the positive Phase 2b results announcement of XF-73 in the prevention of post-operative staphylococcal infections. The fundraising puts Destiny in a much stronger position in both these discussions.

NTCD-M3's Competition thins

Recently,competitors to NTCD-M3 have faltered. **Pfizer's** *C.difficile* toxin vaccine to prevent CDIs failed this primary endpoint in Phase 3. This shows that the prevention of not every infection is tractable by traditional vaccines. For novel and more difficult indications like CDIs, new approaches like a microbiome-directed approach are needed; but unfortunately for Destiny's microbiome competitor **Finch**, safety concerns meant the FDA placed their Phase 3 study on clinical hold.

Model and valuation changes

We have made a number of changes to our valuation and model. Before the fundraising, our valuation was £187.9m or 314p per share. With the cash raised and resulting dilution, this changed to £189.9m or 261p per share, now assuming a FY 2022 cash burn. We have then updated our model by advancing the milestones and royalties received to 2022 for NTCD-M3 (and 2023 for XF-73), and the costs incurred, by a year (to FY 2022). In doing this, we removed the FY 2021 expenses since they are now spent, while risk-adjusting 2022 costs at 100% (since we expect them to be incurred this year) but have maintained the risk-adjustment to the milestones and royalties because a transaction has yet to be announced.

The fundraising, dilution and model changes have resulted in our valuation changing from £187.9m or 314p per share to £210.3m or 289p per share.

Once any transaction has been announced, our risk-adjustment changes and together with the value of the transaction, means further changes to our valuation are likely.

Summary Financials

£'000s, y/e 31 December	2018A	2019A	2020A	2021E	2022E
Revenues					
EBIT	-6,084	-5,585	-6,553	-5,947	-9,508
Basic EPS (p)	-11.9	-10.8	-12.0	-8.6	-11.9
Net Assets	12,257	7,759	12,436	7,893	4,440
Net Cash	12,061	7,480	9,744	5.329	1,876*

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

Company Data

EPIC	DEST
Price (last close)	51p
52 weeks Hi/Lo	189p / 49p
Market cap	£42m
ED Fair Value - per share	£210.3m 289p
Estimated net cash*	£1.9m
Avg. daily volume	28,251

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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Competitors to NTCD-M3 stumble

Pfizer were developing a traditional two- or three- dose vaccine that used the inactivated toxins of *C.difficile* in an injectable product. The CLOVER study was a very large 17,523-patient Phase 3 study that measured CDIs within 14 days and then up to 3 years. The primary endpoint of the study – the prevention of CDIs – was not met, with vaccine efficacy (VE) up to 14 days after the third dose of 49%. VE declined slightly when measured over one and two years. Destiny Pharma's NTCD-M3 microbiome product is an orally dosed and locally-acting product to prevent CDIs with a different mechanism of action to Pfizer's product which raises systemic antibodies to the *C.difficile* toxins.

It is difficult to cross-compare between different studies and different efficacy measures but logically, VE would be the reciprocal of recurrences. **NTCD-M3 has demonstrated a recurrence rate of just 5%** (against 30% for placebo-treated patients) in Phase 2. Pfizer has not released the VE of the placebo arm in CLOVER but has stated that its vaccine met at least two of the secondary endpoints.

This is a disappointment for Pfizer but probably not a surprise because like the coronavirus pandemic – where new mRNA vaccines came to the fore – not all infectious diseases can be prevented by a traditional systemic vaccine. Indeed, had this been possible, a traditional vaccine to prevent CDIs would have almost certainly been approved before now Some difficult unmet medical needs will eventually be met by non-traditional preventative methods like, for example, Destiny's single species NTCD-M3 microbiome approach.

Not all microbiome approaches are the same

On the same day as Pfizer's announcement, a more direct competitor to NTCD-M3 in the microbiome space – Finch Therapeutics' CP101 – had its Phase 3 study placed on clinical hold by the FDA. Unlike Destiny's single species NTCD-M3 product, CP101 is a multi-species consortium of bacterial spores derived from healthy volunteers and the safety and exact definition of consortium products has always been a concern. There has always been the possibility that products like CP101 could include a pathogenic species - and the FDA has requested additional information about Finch's donor screening protocols.

Our expectations for Destiny continue to be a partnering transaction in FY 2022 and the problems at Destiny's potential competitors can only enhance those prospects. Our model and valuation now reflect such a transaction this year.

Income Statement & Forecasts

£'000s, y/e 31 December	2018A	2019A	2020A	2021E	2022E
IFRS Income Statement					
Total revenue					
Administration expenses	-1800	-1887	-1925	-2100	-2100
R&D	-3546	-3800	-4500	-3816	-6866
Other income (expense)		306	12		123
Share-base payments & exceptionals	-738	-204	-139	-25	-210
Depreciation & amortisation	-4			-6	-2
Reported EBIT	**-6084**	**-5585**	**-6553**	**-5947**	**-9508**
Reported profit before tax	**-6008**	**-5521**	**-6481**	**-5929**	**-9450**
Taxation	841	813	1070	800	800
Reported Net income	**-5167**	**-4708**	**-5411**	**-5129**	**-8650**
Basic EPS (p)	-11.86	-10.75	-11.97	-8.58	-11.89
Diluted EPS (p)	-11.86	-10.75	-11.97	-8.58	-11.89

Source: Company historic data, ED estimates

Balance Sheet & Forecasts

£'000s, at y/e 31 December	2018A	2019A	2020A	2021E	2022E
Assets					
Non-current assets					
Tangible assets	30	33	26	40	40
Intangible assets			2261	2261	2261
Total non-current assets	30	33	2280	2301	2302
Current assets					
Trade and other receivables	931	911	1172	547	547
Cash and equivalents	7061	7480	9744	5329	9229
Total current assets	13028	8525	11425	6484	10383
Total assets	13058	8557	13705	8785	12685
Equity and liabilities					
Equity					
Ordinary shares	436	439	598	598	663
Share Premium	17292	17296	27086	27091	33692
Retained earnings	-5471	-9976	-15247	-19796	-27914
Equity attributable to the company	12257	7759	12436	7893	4440
Total equity	12257	7759	12436	7893	4440
Current liabilities					
Trade and other payables	404	514	726	349	349
Total current liabilities	802	798	1268	892	892
Total non-current liabilities					
Total equity and liabilities	13058	8557	13705	8785	12685

Source: Company historic data, ED estimates

Cash Flow Statements & Forecasts

£'000s, y/e 31 December	2018A	2019A	2020A	2021E	2022E
Profit before taxation	-6008	-5521	-6481	-5929	-9450
Depreciation & amortisation	10	18	17	6	2
Share-based payments	738	204	139	211	210
Movements in working capital	381	-83	91	249	0
Net cash generated by operating activities	-4721	-4631	-5492	-4411	-8496
Investing activities					
CapEx on tangibles & intangibles	-18	-21	-2264	-28	0
Other investing activities	76	5063	27	18	59
Net cash used in investing activities	58	5043	-2192	-10	-1412
Financing activities					
Proceeds from issue of shares		7	9949	6	6455
Movements in debt					7353
Net cash from financing activities		7	9949	6	13807
Cash & equivalents at beginning of year	11724	7061	7480	9744	5329
Cash & equivalents at end of year	**7061**	**7480**	**9744**	**5329**	**1876***

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

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