Destiny Pharma plc

A group transformed

10 November 2020

While completing the Phase 2b study of their first product, Destiny have announced the acquisition of an exciting late-stage preventative product and a fundraising to support its Phase 3 development. Along with the previously announced agreement with SporeGen on the preventative therapy for COVID-19, Destiny's portfolio has been transformed by its business development spurt. Furthermore, its cash runway will be extended out by at least a year.

New deal, but same strategy for infection prevention

Investors will be familiar with the preventative indication for Destiny's first product – XF-73 to reduce post-surgical staphylococcal infections – and the recently announced collaboration on a novel microbiome product to prevent COVID-19 infections. Destiny have now announced the acquisition of the global rights to a Phase 3-ready preventative biotherapeutic product that catapults Destiny's pipeline **into late stage development** whilst reinforcing its strategic bent on **preventative microbiome-promoting** therapies. The acquisition of the global rights to non-toxigenic *Clostridiodes difficile* strain M3, which **resulted in 95% prevention of infection recurrence in patients** in Phase 2, and the associated fundraising will transform Destiny and further distance it from the valid critiques levelled at biotech companies that develop new antibiotics.

Fundraising supports ambition

Destiny have announced, subject to GM approval, a conditional placing and Open Offer of up to £11.5m to fund the acquisition and development of M3, including finalising manufacture, and general working capital expenses. The Phase 3 study protocol of M3 was confirmed with the FDA in July 2020 and will be 800 patients randomised 2.2:1 active to placebo. Updating our model, we include these costs and upside from M3's licensing and assume the full £11.5m will be raised.

Valuation updated

The new risk-adjusted NPV model of Destiny Pharma is based on the costs, licensing and milestone revenues of XF-73 and M3, and the cash position after the fundraising. We assume that Destiny will license XF-73 and M3 in 2021 and 2023, respectively, with launches in 2024 and 2025. After the Phase 2b study results in Q1 2021 we expect to update our model for Destiny again, as it will then be a company **with two Phase 3-ready clinical assets**. **Subject to completion, our valuation of Destiny Pharma increases from £84.5m (193p per share) to £138.0m (224p per share).**

Summary Financials

£'000s, y/e 31 December	2017A	2018A	2019A	2020E	2021E
Revenues					
EBIT	-3,222	-6,084	-5,585	-5,851	-5,944
Basic EPS (p)	-8.45	-11.86	-10.75	-8.09	-8.13
Net Assets	16,686	12,257	7,759	14,274	9,292
Net Cash	16,724	12,061	7,480	12,476	7,104

Source: Company historic data, ED estimates (that assume GM approval, EIS & VCT relief qualification, full take-up of Open Offer)

EPIC	**DEST**
Price	66p
52week Hi/Lo	115p / 29p
Current market cap	£30m
ED valuation / per share*	£138m 224p
Est. net cash FY'20*	£12.5m
Avg. daily volume	61,075

**Deal assumptions as listed*

Share Price, p

Source: ADVFN

Description

Destiny Pharma (Destiny) is a clinical development-stage biotechnology company developing novel anti-infectives to prevent and treat infections caused by sensitive and resistant bacteria.

Destiny's proprietary drug discovery platform has generated a number of active antimicrobials including its lead drug XF-73. XF-73 is currently in 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.

Destiny's shares are listed on the UK London Stock Exchange's Alternative Investment Market.

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A genuinely transformative acquisition

Destiny Pharma is a clinical-stage biotechnology company developing novel anti-infectives to prevent and treat infections caused by sensitive and resistant bacteria.

Destiny's proprietary drug discovery platform has generated a number of active antimicrobials including its drug XF-73. XF-73 is in a Phase 2b clinical study under a US IND for the prevention of staphylococcal post-operative infections with results expected in Q1 2021. Destiny recently updated the market on the progress of the Phase 2b study on October 12 with 101 patients out of a total of 125 recruited. XF-73 is active against many antibiotic-resistant bacteria.

In the space of a few months, Destiny have augmented what was its most advanced product, XF-73, with a microbiome collaboration aimed at developing a preventative therapy for COVID-19 that stimulates the innate immune system, and now the acquisition of a Phase-3-ready biotherapeutic product for the prevention of *C. difficile* infection (CDI) recurrence.

With increasing numbers of hospitalised patients (in part, due to the coronavirus pandemic) and with many of them suffering secondary bacterial infections, the increased administration of broad-spectrum antibiotics is to be expected. One of the side-effects of broad-spectrum antibiotic administration is the disruption of the balance of patients' protective gastro-intestinal flora, or microbiome. In the first instance, this typically leads to diarrhoea in hospital-admitted patients, then, the ecological niche in the flora of the bowel cleared by the antibiotics is taken up by an overgrowth of toxigenic strains of *C. difficile* whose hardy spore forms had resisted the actions of the antibiotics. This results in some 500,000 CDI cases per year in the US alone. This can result in toxin-mediated severe diarrhoea and colitis that can have a mortality rate of c. 25% in frail and elderly patients and has been linked to 29,000 US deaths each year.

Once diagnosed, narrow spectrum antibiotics such as vancomycin can be used to eliminate the toxin-producing *C. difficile* overgrowth, however a first recurrence rate (RR) of CDI has been reported to be between 15-35% of initially infected patients.

NTCD M3

The non-toxigenic *C. difficile* strain M3 is a naturally occurring *C. difficile* spore-forming strain without the genes responsible for toxin production. The administration and temporary colonisation of the lower bowel by M3 in Phase 1 and Phase 2 studies resulted in M3 outcompeting and reducing the ecological niche that would be exploited by toxigenic *C. difficile* strains and thus a significant reduction in CDI RR.

Faecal colonisation with M3 occurred in 69% of patients receiving the highest dose of spores in the randomised double-blind placebo-controlled Phase 2 study and diarrhoea and abdominal pain were reduced compared to placebo.

A RR of only 5% was seen in patients, (i.e. 95% prevention), with the highest (10^7) dose of M3 spores compared to 30% in placebo-treated patients ($p=0.01$)[1]. This will be the dose for Destiny's Phase 3 study.

[1] *JAMA*. 2015;313(17):1719-1727. doi:10.1001/jama.2015.3725

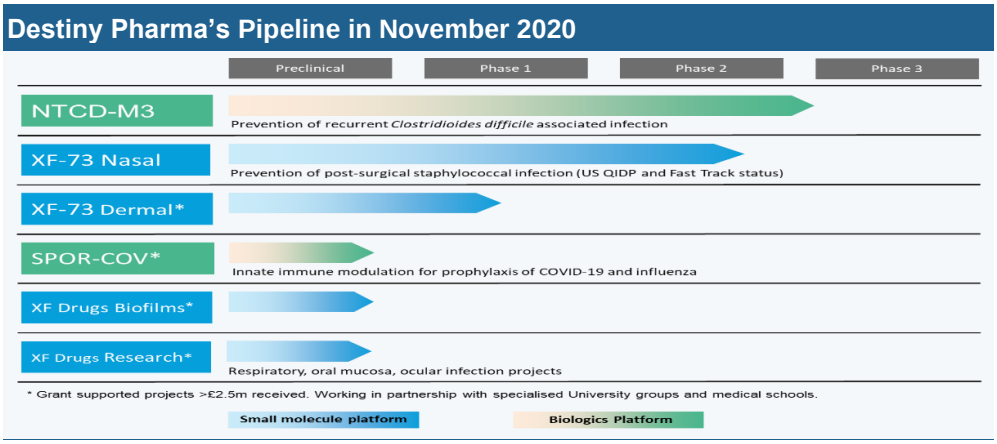
The primary endpoint of the Phase 2 study was safety and tolerability and **M3 was well-tolerated and appeared to be safe**. From a microbiome perspective, strain M3 appeared not to be detected in even the patients with the highest dose after 18-26 weeks of follow-up after M3 had suppressed the toxigenic *C. difficile* strains during the 14-day treatment period.

This is great validation for the microbiome hypothesis where disruption of the normal flora can lead to disease but mechanisms to restore a normal flora result in a reduction of RR. CDI recurrence in the placebo arm was similar to the literature at 30% but only 5% for patients receiving 10^7 spores of M3 for 7 days.

Destiny adds value to M3, which enhances its pipeline

As a promising biotherapeutic preventative therapy, Destiny has licensed the global rights to M3 where most other companies would have failed to recognise the opportunity. This is because of the stigma that is quite rightly applied to the commercial failure of a range of new antibiotic therapies. As we pointed out in our initiation note of Destiny Pharma, the recent approvals of new antibiotics have failed commercially because they are held in reserve for the treatment of the much smaller number patients with diagnosed resistant infections, and prescribed after the failure of first-line empiric standard of care. First-line empiric antimicrobial therapy is almost always cheap and generic. From the very beginning, Destiny has been developing its novel antimicrobial agents for preventative indications, and where there is no on-label standard of care.

The licensing of M3 is also a nod to Destiny's emerging microbiome strategy as the Phase 1 studies of XF-73 have shown the knock-down of *Staphylococcus aureus* nasal carriage, but then restoration of the normal nasopharyngeal flora after a few days. This is similar to the effect seen with M3 in the Phase 2 study where the complex lower gastrointestinal flora seems to be restored without the overgrowth of the toxigenic *C. difficile* strains that result in CDI.



Source: Destiny Pharma

Destiny have been working on the licensing of M3 for about 18 months and in that time, in addition to negotiating the license, Destiny have added value to the project by selecting and qualifying two (primary and secondary) GMP manufacturing facilities, participating in two Type C meetings with the FDA in order to define the protocol for the Phase 3 study and updated M3's chemistry, manufacturing and controls (CMC) to include the change of formulation from the liquid formulation that was used in Phase 2, to a much more convenient and stable capsule dose format for Phase 3.

As a result of Destiny's clinical, technical and business development efforts, its pipeline (shown in the Exhibit above) will have been transformed, and we anticipate that when the Phase 2b results for XF-73 are announced in Q1 2021, Destiny will **be a well-funded company with two Phase 3-ready products.**

M3 is a single-species, bacterial spore product (a biotherapeutic) that Destiny have already worked on to develop an oral capsule formulation. This has the advantages of being a biological product with twelve years of marketing exclusivity (in our model), a very long shelf life and a low cost of goods. With the CMC work that Destiny have already conducted, there is the potential for the generation of addition intellectual property and an extension of its use into all CDI patients (potentially for both primary prevention and multiple recurrence) most of which we have not included in our forecasts.

Financials

We have updated Destiny's financials for the announcement of full proposed amount of the fundraising and a new share count. In addition, the cost of M3's global license is $3m upfront and a further $2m to be paid at the start of the Phase 3 study. For now, we have added these two payments to goodwill on Destiny's balance sheet (and our NPV) and made corresponding acquisition investment values in the cash flow statement.

When the exact amount raised from the open offer net of costs is known, and the goodwill value of M3 net of any fair value adjustments are known, we will be able to again update our financials. This will probably be at the time of Destiny's YE 2020 results. We assume a slight increase in our administration costs after FY2020 onwards, and a significant increase in R&D costs from FY2021.

Our valuation, updated for M3

We have used Destiny Pharma's cash and a risk-adjusted NPV model to value Destiny. This results in a valuation of £138.0m, or 224p per share based on the use of XF-73 and M3 in the prevention of staphylococcal post-surgical infections in high-risk surgical patients, and the prevention of CDI recurrences, respectively.

Risk-adjusted NPV valuation summary

	NPV (£m)	Probability of success	Probability of license	rNPV (£m)	rNPV (p/share)
XF-73 royalty payments (between 2024-36)	367.0	35%	70%	71.1	115
XF-73 milestone payments (£190m over 2021-28)	71.2	35%	70%	17.4	28
M3 royalty payments (between 2020-37)*	75.2	70%	70%	29.1	47
M3 milestone payments (£190m over 2020-37)*	54.2	70%	70%	19.6	32
Costs of XF-73 & M3 development & R&D up to 2036	(22.7)	100%	100%	(11.7)	(19)
Net Cash	12.5	100%	100%	12.5	20
Total valuation	**557.5**			**138.0**	**224**

Source: Company data and ED estimates (that assume GM approval, EIS & VCT relief qualification, full take-up of Open Offer)
**Net of pass-through milestones and royalties*

Since our initiation of Destiny Pharma, our valuation was been based only upon the value of XF-73, and Destiny's cash. We have now updated our valuation as a result of the licensing of M3 to include a risk-adjusted NPV valuation of M3, and Destiny's approximate cash after a successful offering.

The new assumptions in our model include:

As there are different data sources for CDIs in the US, Europe and Japan, we have used the reliable data on the number of reported US hospital and community CDIs, and forecasted them forward as a function of UN population forecasts. First episodes of CDI in the US total approximately 500,000 cases per annum. Of these, first recurrences of CDIs in the US have been reported in between 15-35% of US CDIs. We have used the upper end of this range as the lower rate is a function of lower historical levels of testing and detection (in the same way as it was in the first coronavirus pandemic wave).

Similar published data is used for the EU except using OECD population forecasts. However, Japan's published CDI incidence is calculated per 10,000 hospitalised patient days. We have taken MHWL data on the number of Japanese hospital admissions and the average length of a hospital day in Japan (16 days) and forecasted this using OECD population forecasts (which decline for Japan over the forecast period). First CDI recurrences in Japan have been reported in 17.8% of initial CDI episodes[2].

Our assumption is of a 50% market share of all CDI first episodes/recurrences and half of the newly diagnosed CDI patients (excluding the recurrent patients), but growing from 0.6% market share in the first year of launch to peak at 50% after six years using a Gompertz function. We estimate 12 years of orphan drug exclusivity and no sales in each of the three markets after 12 years of the launches there.

A conservative pricing target of $1,600 per course is in the forecast, which is cheap compared to the approved standard of care Zinplava (bezlotoxumab) – which had a 16.5% reduction in CDI recurrence in Phase 3 compared to 26.6% for placebo – and costs approximately $3,700 per course. CDI recurrence is associated with extended hospitalisation for one to three weeks as second-line antibiotics and Zinplava are administered. This provides a compelling pharmacoeconomic argument as US hospital stays cost at least $20,000 per day.

In our view, M3's launch will be in 2025 in the US, and in Japan and Europe in 2026. We anticipate that Destiny will license M3 in 2023 and its partner will pay a $20m up-front milestone and subsequent milestones (totalling $190m, the same total for XF-73) being sales dependent.

We have also assumed that Destiny will receive a 10% royalty on global sales, and our NPV includes milestones and royalties payable to Destiny net of pass-through milestones and royalties as a result of the M3 license. Our non-risk-adjusted or time discounted milestone total to Destiny net of pass-through milestones is $144m. We also estimate the costs of M3's development until approval based on the number of patients in the single Phase 3 study that the FDA has requested in order to approve M3 for the prevention of CDI after a first episode/recurrence (800), and Destiny's historical clinical trial costs per patient to date.

[2] J Infect Chemother 25 (2019) 615e620

Our model has also been updated for the changes in USD:GBP exchange rate, Destiny's approximate cash and shares in issue as a result of a successful offering, and our expectations for the costs of M3's Phase 3 development. It should be noted that our rNPV valuation is not as simple as the non-risk-adjusted NPV because, for prudence, we have not risk-adjusted the costs of either XF-73 or M3 until their expected licensing because we regards that these costs will have to be incurred in order for the products to be licensed.

Valuation

Our valuation of Destiny Pharma increases from £84.5m (193p per share) to £138.0m, or 224p per share, upon the acquisition of M3 and completion of the full fundraising.

Forecasts

Consolidated Income Statement & Forecasts

£'000s, y/e 31 December	2017A	2018A	2019A	2020E	2021E
IFRS Income Statement					
Total revenue					
Administration expenses	-1011	-1800	-1887	-1150	-2100
R&D	-387	-3546	-3800	-4600	-3816
Other income (expense)	-613		306	25	
Share-based payments & exceptionals	-710	-738	-204	-117	-25
Depreciation & amortisation	-2	-4		-9	-2
Reported EBIT	**-3222**	**-6084**	**-5585**	**-5851**	**-5944**
Reported profit before tax	**-3211**	**-6008**	**-5521**	**-5825**	**-5807**
Taxation	234	841	813	839	800
Reported Net income	**-2977**	**-5167**	**-4708**	**-4985**	**-5007**
Basic EPS (c before 2019, p after 2019)	-8.45	-11.86	-10.75	-8.09	-8.13
Diluted EPS (c before 2019, p after 2019)	-8.45	-11.86	-10.75	-8.09	-8.13

Source: Company historic data, ED estimates (that assume GM approval, EIS & VCT relief qualification, full take-up of Open Offer)

Consolidated Balance sheet & Forecasts

£'000s, at y/e 31 December	2017A	2018A	2019A	2020E	2021E
Assets					
Non-current assets					
Tangible assets	22	30	33	26	24
Intangible assets					
Goodwill				2308	2308
Total non-current assets	22	30	33	2333	2332
Current assets					
Trade and other receivables	277	931	911	560	277
Cash and equivalents	11724	7061	7480	12467	14796
Total current assets	17061	13028	8525	13043	15089
Total assets	**17083**	**13058**	**8557**	**15376**	**17421**
Equity and liabilities					
Equity					
Ordinary shares	436	436	439	723	723
Share Premium	17292	17292	17296	28512	28537
Retained earnings	-1042	-5471	-9976	-14961	-19968
Equity attributable to the company	16686	12257	7759	14274	9292
Total equity	16686	12257	7759	14274	9292
Current liabilities					
Trade and other payables	-152	-404	-514	-818	-152
Total current liabilities	-397	-802	-798	-1,102	-436
Total non-current liabilities					-7692
Total equity and liabilities	17083	13058	8557	15376	17419

Source: Company historic data, ED estimates (that assume GM approval, EIS & VCT relief qualification, full take-up of Open Offer)

Consolidated Cash flow Statement & Forecasts					
£'000s, y/e 31 December	**2017A**	**2018A**	**2019A**	**2020E**	**2021E**
Profit before taxation	-3211	-6008	-5521	-5825	-5807
Adjustment for:					
Depreciation & amortisation	2	10	18	9	2
Movements in working capital	165	381	-83	656	-383
Share-based payments	710	738	204	117	25
Net cash generated by operating activities	-2153	-4721	-4631	-4230	-5500
Investing activities					
Acquisitions				-2308	
Capital expenditure on tangibles	-23	-18	-21	-2	
Other investing activities	-4990	76	5063	27	137
Net cash used in investing activities	-5013	58	5043	-2283	137
Financing activities					
Net proceeds from issue of shares	17409		7	11500	
Movements in debt					7692
Net cash from financing activities	17409		7	11500	7692
Cash & equivalents at beginning of year	1481	11724	7061	7480	12467
Cash & equivalents at end of year	**11724**	**7061**	**7480**	**12467**	**14796**

Source: Company historic data, ED estimates (that assume GM approval, EIS & VCT relief qualification, full take-up of Open Offer)

Investor Access

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