Destiny Pharma plc

Bucking the Big Pharma trend

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Destiny Pharma (DEST) is focused on developing innovative drugs with the potential to prevent or treat prevalent forms of drug resistant infection. Lead asset XF-73 has potential to be first to a $1.2bn core market. We think that its low propensity to trigger Antimicrobial Resistance (AMR) seen in testing to-date means the strong commercial rationale for XF-73 bucks the trend which has caused a steady retraction in Big Pharma antimicrobials pipelines.

- In FY18 DEST made progress on achieving its strategic aims including delivering two successful Phase I skin irritation studies for lead program XF-73 a topical gel for intranasal delivery targeted at a new FDA-backed indication for prevention of post-surgical *S aureus* infection. These studies demonstrate XF-73 has a benign safety profile, fulfilling the requirements needed to initiate the placebo-controlled randomised Phase IIb study in post-surgical *S aureus* infection which is to commence imminently.
- XF-73 has low propensity to trigger Antimicrobial Resistance (AMR) meaning that the drug can be used for high risk surgery to replace mupirocin which is routinely employed off-label in US in pre-surgical prep for *S aureus* carriers, but which has led to rates of resistance up to 95% in some cases.
- The high priority placed on the fight against AMR has recently been highlighted yet again by a range of political incentives which include planned additional investment by the UK Government in its 5-year action plan and with further recognition from US FDA Commissioner Gottlieb calling for new tools to meet the AMR challenge.
- The Company ended FY18 with a strong cash position of £12.1m having managed expenses tightly including £3.5m of R&D expenditure, providing a cash reach into 2020 on our forecasts and covering the cost of the Phase IIb trial. Further non-dilutive funding includes the award of up to £1.6m under the UK-China AMR programme for drug discovery with an ocular and dermal focus and is further validation of the XF platform.
- The prospects of partnering XF-73 to take it forward from Phase IIb in the event of positive clinical outcomes appear to be favourable given the scarcity of novel alternatives and given the recent Big Pharma *S aureus* vaccine failures - including Pfizer, Merck and GSK.

We increase our SOTP DCF valuation marginally to £131m updating for cash, FY18 results and with rolling forwards: equivalent to 301p / share.

We also note that shares have underperformed since IPO, falling around 60%. By contrast, the imminent launch of the Phase IIb study is likely to be a key catalyst for revaluation and so we reiterate that at current share price offers a compelling entry point into a novel and commercially attractive antimicrobials pipeline.

Company Data

EPIC	AIM:DEST
Price	84p
52 week Hi/Lo	129p / 60p
Market cap	£37m
ED value/share	301p

Share Price, p

Source: ADVFN

Description

Destiny Pharma is a UK-based clinical stage developer of medicines for the prevention and treatment of infections caused by drug-resistant bacteria. There are three candidates in development from the XF Drug series, the most advanced is about to enter Phase IIb studies in Prevention of postsurgical Staphylococcal infection and with a range of discovery partnerships in place.

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XF Pipeline	
XF-73 Nasal – FDA awarded QIDP and fast track status / Phase IIb	Prevention of post-surgical staphylococcal infection
XF-73 Dermal / Phase I	Treatment of antibiotic resistant skin infection – diabetic foot ulcers DFU/burns wounds
XF Throat / Pre-clinical	Prevention of staphylococcal hospital/ventilator associated infection
Discovery programmes	Treatment of bacterial biofilm associated infections

Source: Destiny Pharma

The soon-to-be-launched Phase IIb FDA randomised, placebo-controlled study of XF-73 targets up to 200 patients with planned recruitment across up to 22 sites in the US and Georgia. High risk patients will be enrolled including heart surgery candidates – and with the target of recruitment completion over a six-month period – leading to readout around the end of 2019. FDA is fully supportive of the Phase IIb protocol.

The study design is planned across four main stages;

- Screening patients to confirm *S aureus* carriage;
- Randomisation to XF-73 or placebo;
- Patients will receive up to 4 applications of XF-73 prior to surgery – followed by a further application immediately after surgery. The measurement of the primary endpoint of *S aureus* burden will be made prior to the procedure via nasal swab; and
- With follow up at 30 days or 90 days for patients receiving implants.

The follow up will enable monitoring of incidence of post-surgical infection, although the primary endpoint is microbiological or a reduction in the count of bacterial colonies. Infection rates will be measured along with a range of other secondary endpoints by a Data Monitoring Committee, a requirement to limit risk in the placebo arm.

Sound commercial rationale

In our view, XF-73 has potential for broad adoption in the prevention indication because of its favourable resistance profile; the build-up of mupirocin resistance limits use. This is supported by other factors including the shorter dosing regimen which can be completed in 24 hours - compared to 5 days advised for the predominant but unlicensed mupirocin. This means that XF-73 can be potentially used for spontaneous surgical cases and makes for a more convenient and potentially less costly preparation routine. Views from payors and hospital pharmacy directors have been favourable according to interviews conducted to-date.

Our commercial estimates are based on adoption across a core high volume market in high-risk surgery for carriers of *S aureus*. If we assume that patients will be routinely screened, with an average of one third being carriers of *S aureus* and therefore candidates for targeted decolonisation, then that equates to a pool of around 6m patients per annum in the potential core market alone. Using existing mupirocin pricing, five-day dosing cost of c $200, and an estimate of market penetration at 50% provides our peak sales of $0.6bn.

A secondary market is for Universal Decolonisation - patients who are non-carriers. We calculate peak sales of $244m at 10% penetration in the UD market.

There is scope for higher pricing for both indications given the premium for a first in class and first to market drug, the potential for broader cost–savings in achieving hospital infection control targets and lowering the cost burden of infection rates. This is supported by initial market research conducted by DEST.

Fuelling a growing pipeline

The next most advanced program is XF-73 in dermal indications - treatment of antibiotic resistant skin infection in diabetic foot ulcers (DFUs)/burns wounds. The rationale here follows on from Phase I study results showing that XF-73 is a suitable treatment for longer term treatment. This will be confirmed during additional Phase I studies planned in 2019, targeting the completion of a Phase II ready package in during 2020. An estimated 24 million people in the US suffer with diabetes and around 1.5 million new cases develop each year.

The chronic nature of DFU can increase the likelihood of infections and *S aureus* including MRSA were seen to be key pathogens in DFU infection. MRSA is reported to be responsible for an increase in healing time of over three times compared to methicillin sensitive strains and Gram-negative strains are associated with longer duration of infection.

Therefore, there is a clear rationale for XF-73 owing to its demonstrated activity against both Gram-negative and Gram-positive pathogens and which can be enhanced using photodynamic therapy (PDT).

It is early days and DEST will continue to work on formulating and testing XF-73 ahead of a targeted Phase II study start in 2020 in consort with its new expert topicals formulation partner, MedPharm. If outcomes are positive it suggests that the drug might be widely used – as in the nasal indication - particularly if it can be used to provide both a treatment and potential preventative approach given the limitations of current options.

We calculate that of a potential patient pool of around 0.4m diabetics - up to 25% of sufferers will develop DFU in both feet taking our peak global sales estimate to $500m at an average cost per course of treatment of $1,000 (Company data). We estimate that DEST could achieve up to 40% market penetration if ongoing studies yield positive data and given the scale of the unmet need.

In our opinion, the clinical rationale for introducing a new drug to help combat drug resistant pathogens in moderate to severe burns wounds is also well supported. The number of hospital admissions for burns wounds is approaching 90,000 per annum in the US according to the CDC with at least 60% of these people at risk of infection due to hospitalisation - equivalent to at least 70,000 patients in the US.

Infection is the most common cause of morbidity and mortality in this population, with almost 61% of deaths caused by infection.

With earlier stage potential lining up...

There are additional programs at the preclinical stage – DEST is investigating the potential of a preventative approach for Ventilator or Hospital Associated Pneumonia – where the main pathogens involved are *S aureus* and *P aeruginosa* – this is likely to include a spray to administer the drug to the throat.

The rationale is supported by studies that have shown a link between MRSA colonisation and a higher likelihood of isolation of MRSA from respiratory samples with unmet need based on an incidence of around 300,000 cases. We await further news before adding this indication into our forecasts, including potential grant of QIDP status in the indication.

Destiny Pharma is also accelerating research into the potential to combat biofilm associated infections by means of its research collaborations including with Aston University – and more recently with the University of Southampton- to investigate infections in diabetic foot ulcers and cystic fibrosis. Biofilms, which are formed from a layer of impermeable slime which coats and encloses bacteria, pose an increased risk when treating infection since they are generally highly resistant to treatment. DEST identified that XF-70 has *in vitro* activity against biofilms – and was granted a US patent for using XF drugs in biofilms in 2016.

There are also exciting prospects and further validation of DEST's novel approach – issuing from the drug discovery research collaboration UK-China AMR programme with Cardiff University and Tianjin Medical University. This is to be funded jointly by Innovate UK, the Department of Health and Social Care and the Chinese Ministry of Science and Technology and seeks to identify new drug candidates for dermal and ocular indications.

Financials

DEST increased its R&D activities in FY18 along with headcount to support its accelerating clinical and scientific progress; total Opex of £5.3m vs £2.5m in FY17 (vs our forecast of £10.5m) including £3.5m in R&D expenses (vs £0.8m in FY17). The company received a payment of £0.2m in R&D tax credit. As a result, operating loss rose to £6.1m vs £3.2m in FY17.

The end of year cash balance of £12.1m was consequently ahead of our forecast of £7m although we judge that this is largely down to timing of the start of the Phase IIb study which is now timed for an April 2019 launch.

Looking forward, we add in £0.5m of grant funding under the UK-China AMR programme into our forecasts over 2019-20 and we estimate that FY19 R&D expenses will be higher than our previous estimate (£4.7m) with the bulk of Phase IIb expenses falling within FY19.

This takes our FY19 total Opex to £10.7m although leaves overall estimated cash reach unchanged into late 2020.

Valuation

Our SOTP DCF valuation /share increases slightly to 301p from 295p – we use a 12.5% WACC and show the breakdown by indication below.

Valuation Summary

	Total £m	*Per share (p)*
XF-73 prevention of post surgical infection, *S aureus* carriers, US	77.6	178.1
XF-73 prevention of post surgical infection, Universal Decolonisation, US	32.2	74.0
XF-73 Universal Decolonisation in emergency surgery cases, US	6.5	15.0
XF-73 DFU/Burns wounds	9.2	21.0
Corporate costs 12 months	-6.3	-14.5
Net cash end December 2018	12.1	27.8
Total	**131.3**	**301.3**

Source: Equity Development

We conclude that underperformance of DEST shares since IPO has led to the current valuation mismatch which appears unwarranted given the progress being made and ahead of key news flow in 2019. There are a range of events that could lead to a revaluation of the shares including:

- Phase IIb study start;
- Entry of new drug candidates into clinical studies;
- News on pipeline and from research partnerships or further clinical news;
- Further potential for grant funding or news on new partners.

Income Statement				
Y/e Dec 31	**2017**	**2018**	**2019e**	**2020e**
£'000s				
Revenues	0	0	250	250
Cost of goods sold	0	0	0	0
Gross Profit	0	0	250	250
R&D Expenses	-800	-3500	-8750	-1050
G&A Expenses	-1712	-1846	-1938	-2035
Sales & Marketing	0	0	0	0
Operating Loss	-2512	-5346	-10438	-2835
Share based payments	-710	-738	-723	-708
EBITDA	-3220	-6074	-11149	-3529
Operating Loss	-3222	-6084	-11161	-3544
Interest income	10	76	14	-5
Other financing costs/income	0	0	0	0
Loss Before Taxes	-3211	-6008	-11147	-3549
Adj. Loss Before Taxes	-2501	-5270	-10424	-2840
Current tax credit	234	841	892	1065
Net Loss	-2977	-5167	-10256	-2484
Average no. of shares, m	35	44	44	44
Loss per share (p)	-8	-12	-24	-6

Source: DEST historic figures/Equity Development Forecasts

Balance Sheet				
Y/e Dec 31 £'000s	**2017**	**2018**	**2019e**	**2020e**
Current assets	17061	13028	3489	1708
Cash and cash equivalents	16724	12061	2509	685
Trade & receivables	277	931	931	931
Inventories	0	0	0	0
Prepayments	60	36	49	92
Non-current assets	22	30	37	42
Property, plant & equipment	22	30	37	42
Intangible assets	0	0	0	0
Current liabilities	-397	-802	-802	-802
Short-term debt	0	0	0	0
Accounts payable & accruals	-397	-802	-802	-802
Non-current liabilities	0	0	0	0
Long-term debt	0	0	0	0
Equity	16686	12257	2724	948
Share capital	436	436	436	436
Other	16250	11821	2288	513

Source: DEST historic figures/Equity Development Forecasts

Cash Flow				
Y/e Dec 31 £'000s	**2017**	**2018**	**2019e**	**2020e**
Net cash from operating activities	-2153	-4721	-9533	-1804
Profit/(loss) before tax	-3211	-6008	-11147	-3549
Non-cash adjustments	702	671	735	723
Change in working capital	165	381	0	0
Interest paid	0	0	0	0
Taxes received	192	234	879	1021
Investing cash flow	-5013	58	-19	-20
CAPEX on tangible assets	-23	-18	-19	-20
Financial investments/other	-4990	76	0	0
Financing cash flow	17409	0	0	0
Proceeds from equity	17409	0	0	0
Increase in loans	0	0	0	0
Net increase in cash	10243	-4663	-9552	-1824
Exchange rate effects	0	0	0	0
Cash at the start of year	1481	16724	12061	2509
Cash at year end	16724	12061	2509	685

Source: DEST historic figures/Equity Development Forecasts

Investor Access

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