

Developing Novel Products that Prevent Life-threatening Infections September 2020

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Building World Leading Company Focused on Preventing Life Threatening Infections



COVID-19 has highlighted to the world the health and economic threat of untreatable infections

- Focus on novel hospital products with strong clinical benefits and commercial potential
- Develop potential blockbuster lead asset XF-73
- Continue to develop pipeline from XF drug platform
- In-licensing and M & A to expand clinical pipeline e.g. Spor-Cov microbiome asset
- Access to China market through partnership with CMS
- Strategic partnering in geographical regions and indications at key inflection points
- Secure additional grant support to help fund vibrant pipeline £2.5 million awarded to date

Highlights



Operational highlights

Phase 2b clinical trial: XF-73 nasal gel for prevention of post-surgical infections

- Protocol amendment agreed with FDA
- Phase 2b XF-73 nasal study recruitment planned to complete by end of 2020
- Protocol amendment agreed with FDA No impact on quality of study and statistical quality of Phase 2b
- Positive interim safety analysis of Phase 2b trial
- Recruitment to complete end of 2020; Data expected Q1 2021

Financial highlights

- Strong cash position with cash and term deposits at 30 June 2020 of £5.6 million (30 June 2019: £9.1 million; 31 December 2019: £7.5 million)
- Expenditure on R&D in the period of £2.3 million (half-year 2019: £1.7 million; full year 2019: £3.8 million) reflecting the increased investment in clinical research
- Funded through to Q4 2021

SporeGen® COVID-19 collaboration

- Co-develop a novel, preventative product for COVID-19
- Majority to be funded by Innovate UK grant award of £800.000
- Expands novel pipeline targeted at preventing infections with novel biologics/microbiome



Financial Overview

for the 6 months ended 30 June 2020

Condensed statement of comprehensive income





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|---------|----|------|------|
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 Loss before tax of £2.9M (H1 2019: £2.5M)

Key drivers:

- R&D spend of £2.3M (H1 2019: £1.7M)
 - lower than expected due to slowdown in nasal study caused by COVID-19
- Admin costs £0.6M (H1 2019: £0.8M)
 - reduction in activity due to COVID-19

| | 6 months ended 30 June 2020 Unaudited £ | 6 months ended 30 June 2019 Unaudited £ | Year ended 31 December 2019 Audited £ |
|--|--|--|---|
| Continuing operations | | | |
| Revenue | - | - | - |
| Administrative expenses | (2,912,801) | (2,556,773) | (5,687,003) |
| Other operating income | 12,450 | 198,474 | 305,906 |
| Share option charge | (58,668) | (109,454) | (203,655) |
| Operating loss | (2,959,019) | (2,467,753) | (5,584,752) |
| Finance income | 13,470 | 40,316 | 63,478 |
| Loss before tax | (2,945,549) | (2,427,437) | (5,521,274) |
| Taxation | 515,378 | 332,413 | 813,250 |
| Loss from continuing operations | (2,430,171) | (2,095,024) | (4,708,024) |
| Loss per share (basic and diluted) - pence | (5.5)p | (4.8)p | (10.7)p |

Condensed statement of financial position

as at 30 June 2020



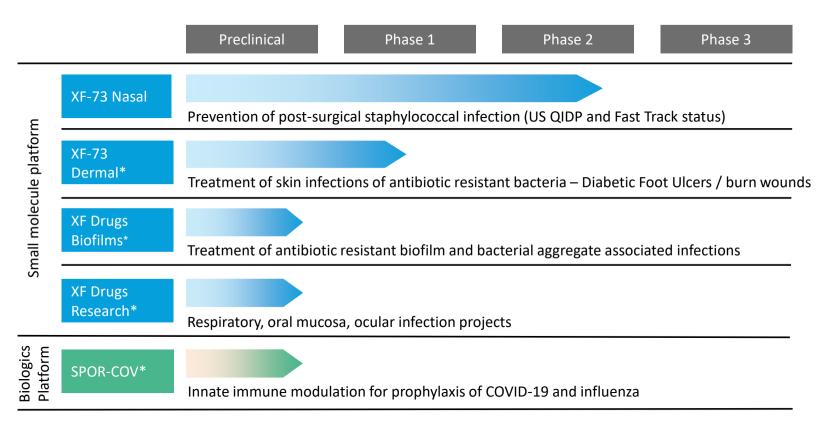
Highlights:

- Net cash outflow of £1.9M (H1 2019: £3.0M)
 resulting in net cash at 30 June of £5.6M
- 2019 R&D tax credit of £0.8M received during the period
- Company remains funded through to Q4 2021

| | 30 June 2020 Unaudited £ | 30 June 2019 Unaudited £ | 31 Dec 2019 Audited £ |
|---|--------------------------------|--------------------------------|-----------------------------|
| Assets | | | |
| Non-current assets: Property, plant and equipment | 25,764 | 38,031 | 32,922 |
| Current assets: Trade and other receivables | 559,747 | 1,259,349 | 911,198 |
| Prepayments and accrued income | 48,192 | 186,157 | 133,702 |
| Cash and cash equivalents | 5,571,631 | 5,077,954 | 7,479,642 |
| Other financial assets (term deposits 3 months+) | - | 4,000,000 | - |
| Total assets | 6,205,334 | 10,561,491 | 8,557,464 |
| Equity and liabilities | | | |
| Equity | | | |
| Called-up share capital | 438,652 | 435,652 | 438,652 |
| Share premium | 17,296,337 | 17,292,337 | 17,296,337 |
| Accumulated losses | (12,347,167) | (7,456,865) | (9,975,664) |
| Shareholders' equity | 5,387,822 | 10,278,124 | 7,759,325 |
| Liabilities | | | |
| Current liabilities | 817,512 | 283,367 | 798,139 |
| Total equity and liabilities | 6,205,334 | 10,561,491 | 8,557,464 |

Pipeline of Novel Treatments to Prevent Infections





^{*} Grant supported projects >£2m received. Working in partnership with specialised University groups and medical schools.

XF-73 - Lead Product with Blockbuster Potential





- XF-73 is uniquely differentiated from current antibiotics highly novel mechanism, clinical profile is compelling, with a strong IP position protecting product franchise into 2030s.
- QIDP status gives 10 years data exclusivity in the US



- Hospital only setting leverages its unique no/low resistance profile.
- Targeted, topical delivery with acute use and no systemic absorption minimises potential tolerability/side effective profile
- Reducing nasal S. aureus carriage reduces post-surgical infection by c.60%



- XF-73 has blockbuster potential favourable pharmaco-economics support the pricing strategy and a strong cost benefit argument, particularly in US
- Inclusion in total surgical cost for reimbursement



- Upcoming significant value inflection point from Phase 2b trial. Recruitment completing 2020, as FDA agreed to protocol amendment. 88 out of 125 now recruited.
- Positive interim safety review.



1 in 3

people carry *S.* aureus

Carriers have 10x higher risk of post-surgical infection

40 million US surgical

patients at risk of post-surgical infection



Annual cost of complications in US due to post surgical infections

<\$10 billion

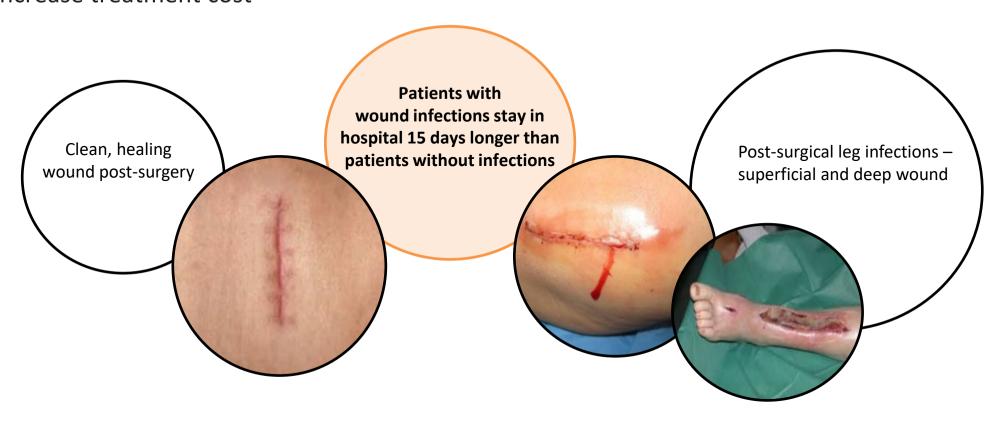
XF-73 target market a

\$1bn

peak sales opportunity

Post surgical infections delay recovery / Increase treatment cost





"The hospital has the biggest financial incentive to reduce post-operative surgical infections and can absorb the [XF-73] cost in the DRG payment"

Quote from independent hospital (US market research 2018)

XF-73 addresses pre-surgical nasal SA decolonisation - a significant, unmet clinical need





No approved drug in US market – current practice:

- Either, no treatment (despite "best practice" recommending decolonisation)
- Or, pre-surgical use of the old GSK nasal antibiotic, mupirocin, as unapproved drug



Significant unmet medical need:

☐ Hospitals incentivised to prevent post-surgical infections & reimbursement simplified



XF-73 addresses this unmet clinical need:

☐ Widespread and prolonged use of mupirocin leads to rapid emergence of S. aureus mupirocin resistance and some hospitals have halted mupirocin use

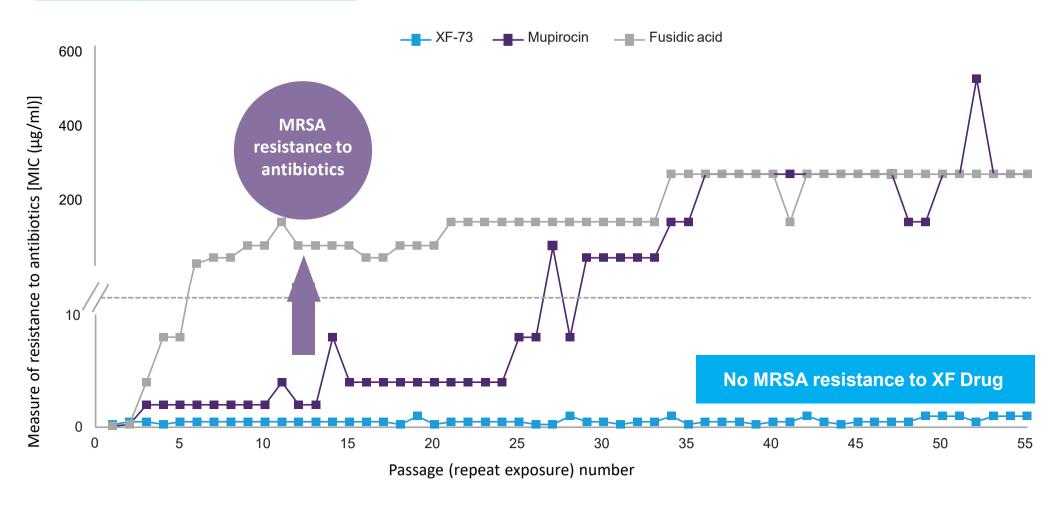
"The use of an effective agent, should be the incentive since it would lower [the cost of] post-operative infections"

Medical Director, California hospital

XF-73 has a unique no / low resistance profile



Supported by 2020 Oxford University review in tackling AMR by R. Craig Maclean Trends in Microbiology DOI - https://doi.org/10.1016/j.tim.2020.03.011



Farrell, et al.; Investigation of the potential for mutational resistance to XF-73, Retapamulin, Mupirocin, Fusidic acid, Daptomycin and Vancomycin in MRSA isolates during a 55-Passage study. Antimicrobial Agents & Chemotherapy (2011); 55; (3) 1177-1181

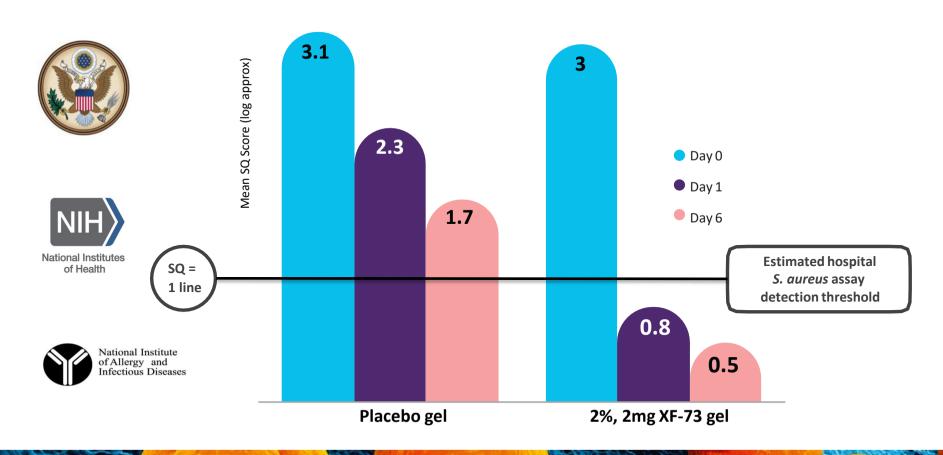
XF-73 delivers rapid & sustained clinical *S. aureus* nasal reduction



Reduction of bacterial burden reduces bacterial infection rate (Datta et al 2014)

Data from US government funded trial in 2016 supports XF-73 as a potential effective preventative agent

S. aureus load after 0, 1 & 5 days dosing. 48 subjects



XF-73 Phase 2b data expected early 2021



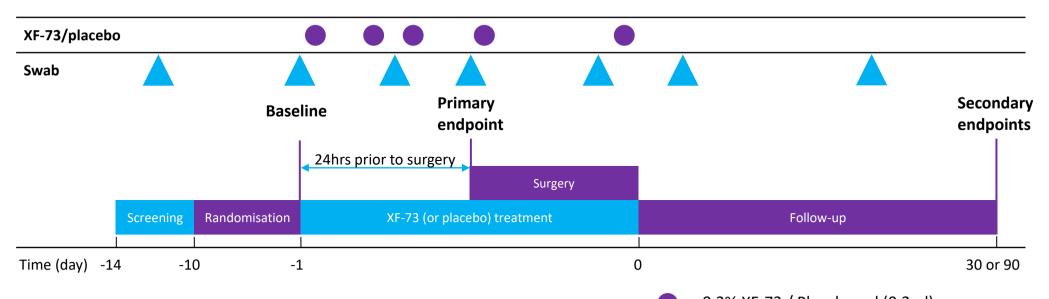
Inclusion criteria

125 heart surgery patients with confirmed nasal *S. aureus* carriage (88 recruited, as of Sept 16, 2020)

Trial Design

Arm A: 5 doses XF-73 nasal gel Arm B: 5 doses placebo nasal gel

Primary endpoint: Reduction in nasal S. aureus burden vs. placebo from baseline to immediately pre surgery



Clinicaltrials.gov identifier: NCT03915470

= 0.2% XF-73 / Placebo gel (0.3ml) per nares

= Nasal swab for quantitative *S. aureus* assessment

XF-73 Phase 2b recruitment completing Q4 2020



| Molecule | XF-73 | |
|--------------------|--|--|
| Indication | Post surgical Staphylococcus aureus infections | |
| Phase | Phase 2b | |
| # of patients | 125 | |
| Inclusion criteria | Heart surgery patients with confirmed nasal S. aureus carriage | |
| Primary endpoint | Reduction in nasal S. aureus burden vs. placebo from baseline to immediately pre surgery | |
| Design | Double blind, randomized, placebo controlled Arm A: 5 doses XF-73 nasal gel Arm B: 5 doses placebo nasal gel | |
| Status | 88 out of 125 patients recruited September 2020 Positive interim safety review August 2020 Estimated recruitment completion end 2020 | |
| Topline data | Estimated Q1 2021. Phase 3 planning underway | |
| Clinicaltrials.gov | NCT03915470 | |

Summary



- Building a world class company focused on novel hospital products with strong clinical benefits and commercial potential
- Completing recruitment in Phase 2 clinical development of lead drug asset, XF-73 at end of 2020
- Data anticipated Q1 2020 major inflection point
- Significant commercial opportunity \$1 billion opportunity in US alone
- Expanded pipeline with SPOR-COV a novel preventative treatment for COVID-19 supported by an £800.000 Innovate UK grant
- The significant healthcare and economic impact of COVID-19 has highlighted the global need for innovation that delivers fast, safe and affordable anti-infection treatments
- Well funded with cash runway that extends to Q4 2021 to execute business strategy and progress follow-on programmes





Management Team



Neil Clark FCA, CEO

Over 20 years in AIM listed biotech/life sciences leadership positions at CeNes and Ergomed



Dr. William Love PhD, CSO

Founder and co-inventor of the XF Drug Platform and recognised thought leader in tackling AMR



Shaun Claydon FCA, CFO

Experienced life science CFO and investment banker/corporate financier



Dr. Jesus Gonzalez MD, CMO

Expert in the design and execution of clinical trials for anti-infective drug candidates. FDA, biotech and pharma experience

Non-Executive Board Members



Nick Rodgers Chairman

Investment banker/corporate financier with extensive broad experience in life science in private and public companies. Ex-Chair of Oxford Biomedica



Peter Morgan
Director

Pharma industry consultant including AIM companies.

Background in product and general management in Ciba Geigy

/Novartis



Dr Huaizheng Peng MDDirector

GM and International Director of China Medical Systems. Background in City fund management and investment banking. Medical doctor by training



Dr Debra Barker MDDirector

Ex-Roche, GSK and, most recently, at Polyphor. Held several senior roles at Novartis. On the board of Hutman Diagnostics and BerGenBio

Independent research in 2019 supports XF-73 market positioning





Mupirocin Resistance in *Staphylococcus aureus*: A Systematic Review and Meta-Analysis

- Dadashi et al 2019
- Prevalence has now increased to 7.6% and mupirocin-resistant MRSAs have significantly increased to 13.8%



Guidelines for Perioperative Care in Cardiac Surgery: Enhanced Recovery After Surgery Society Recommendations

- Engelman et al, 2019
- Article instructs US surgeons to, "Perform topical intranasal decolonization prior to surgery", with the highest IA



New Asian guidelines recommend decolonisation

- Ling et al, 2019
- The APSIC guidelines also support Destiny Pharma's strategic approach in China where it has a regional collaboration with China Medical Systems

XF-73 dermal clinical program

- Destiny Pharma
- XF-73 dermal targeting infections associated with diabetic foot ulcers (DFUs) and burns
- Builds on existing XF-73 nasal data
- Phase 1 safety study completed in abraded skin supports dermal potential
- Plan to deliver Phase 2 ready package with grant supported work in China/UK/US
- XF-73 dermal target product profile tested, current best practice reviewed, and feasibility of clinical development pathway reviewed



Diabetic foot ulcer

Annual cost of DFU care in US is over \$10 billon

~20% of diabetes patients experience DFU

infections >350,000 in US alone

\$0.5bn peak sales opportunity

https://www.ncvh.org/pdf/2015%20NCVH/5-27-Wed/Podiatry/1330 John%20Labovitz revised.pdf

https://diabeticfootonline.com/diabetic-foot-facts-and-figures/

XF-73 offers clear advantages over current standard-of-care



| | Mupirocin | XF-73 | | |
|---------------------|------------------------|--------------|----------|--|
| Pre-op dosing | 5 Days | 1 Day | ······ | Reduces timeframe needed to treat prior to surgery |
| Efficacy | Not All Strains | All Strains | | Targets the entire SA spectrum |
| Resistance Build Up | Yes | No | ······ ✓ | Expands target patient population |
| Administration | Nasal Ointment | Nasal Gel | ~ | Positive effect on compliance |
| Tolerability | Irritant | Non-irritant | | Well-tolerated – positive impact on compliance |
| MoA | Traditional | Innovative | / | Superior efficacy and safety profile |
| Indication | Off Label | Licensed | | Increases potential for adoption onto hospital formulary |

XF-73 is significantly de-risked

7 Phase 1 trials completed in 278 subjects



| Study Title | Sponsor | # of Subjects | Design & Results |
|---------------|----------------------|---------------|---|
| XF-73A01 | Destiny Pharma | 23 | 1st in man, low dose (.075mg/g), 5 days dosing, <mark>safe</mark> |
| XF-73B01 | Destiny Pharma | 45 | Higher dose (.5mg/g), anti-S. aureus effect, 5 days dosing, dose response, safe |
| XF-73B02 | Destiny Pharma | 32 | Higher dose (2.0mg/g), enhanced anti-S. aureus effect, 5 days dosing, safe |
| XF-73B03* | Destiny Pharma | 60 | 2 day dosing, lower viscosity gel, hospital-like procedure, rapid anti-S. aureus nasal effect, safe |
| DMID-11-0007* | US Government Funded | 48 | 5 day dosing, lower viscosity gel, hospital-like procedure, rapid anti-S. aureus nasal effect, safe |
| XF-73B05 | Destiny Pharma | 35 | 5 day dosing, high concentrations, lack of systemic absorption, non-irritant, |
| XF-73B06 | Destiny Pharma | 35 | 21 day dosing, low viscosity gel, no adverse events, safe, well-tolerated |

^{*}Both studies placebo controlled & XF-73 applied as an intra-nasal gel achieved statistical difference for S. aureus reduction

XF pre-clinical and discovery programmes



Research collaborations/grant funding validate XF platform potential

- Grant funded biofilm research projects signed with Aston, Southampton and Sheffield Universities targeting dermal, ocular, oral and respiratory infections
 - Biofilms are a key component in serious infections associated with cystic fibrosis, medical devices, oral conditions, implants and catheters
- Awarded up to £1.6m under UK-China AMR fund
 - Research projects addressing infections (including ocular) and AMR in collaboration with Cardiff University, Tianjin University and Chinese partners
- Seeking to enter further collaborations/grants to extend XF drug platform projects
- Latest microbiology test screens of XF-73 confirms efficacy against 70 of the latest S. aureus and MRSA strains















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