developing science
delivering therapies
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The Microbiome
THE MICROBIOME – THE POTENTIAL

Microbiome

- Trillions of bacteria which colonise the human gut
- More gut bacteria than host cells
- 100x as many genes as the human genome
- Crucial in shaping the host immune system & metabolism

Live Biotherapeutics

- Breakthrough class of medicines
- Myriad therapeutic areas
- Potential to change the way we treat disease
The Microbiome

2012
Full human microbiome profiled; published in Nature

Today
circa 80+ microbiome companies

2005
First LBP clinical trial

2014
4D pharma founded

2019
> 40 clinical programmes expected

The Microbiome

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> 40 clinical programmes expected
4D Research Rationale
## RAPID DEVELOPMENT IN MAJOR THERAPEUTIC AREAS

<table>
<thead>
<tr>
<th>Therapeutic Area</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
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<tbody>
<tr>
<td><strong>Gastro-intestinal</strong></td>
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<td>Blautix <em>Irritable Bowel Syndrome</em></td>
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<td>Thetanix <em>Crohn’s Disease</em></td>
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<td>Rosburix <em>Ulcerative Colitis</em></td>
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<td><strong>Immuno-oncology</strong></td>
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<td>MRx0518 <em>Solid tumours</em></td>
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<td><strong>Respiratory</strong></td>
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<tr>
<td>MRx0004 <em>Asthma</em></td>
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<tr>
<td>MRx0001 <em>Allergic Asthma</em></td>
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<td><strong>Autoimmune</strong></td>
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<tr>
<td>MRx0002 <em>Multiple Sclerosis</em></td>
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<td>MRx0006 <em>Rheumatoid Arthritis</em></td>
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<td><strong>Others</strong></td>
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<tr>
<td><strong>CNS</strong></td>
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<td>Neurodegeneration</td>
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<td>Autism</td>
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Traditional Pharma vs 4D Live Biotherapeutics

Validated targets

Design synthetic structures to ‘drug’ target

Infinite configurations, imprecise and out of context

10 years of development

£200m per drug

Evolution of rational drug design

Validated targets

Different microbiome, common functionality

Identify which bacteria have ‘function’ in context

Millions of years of development

£2m per drug

Evolution
DISCOVERING EVOLVED FUNCTION

- 99% coverage of genera within gut microbiota
- High-throughput screening protocols
- Interaction with human cells
- Comparative genomics, transcriptomics, proteomics, metabolomics, surfaceomics
- Full characterisation of host and bacteria response
- Activity and mechanism in preclinical models

4D Research Rationale

CONFIDENTIAL
Programmes:
MRx0518 – Immuno-oncology
MRX0518 INHIBITS TUMOUR GROWTH

Efficacy in multiple tumour types

- Inhibition of tumour growth in three different preclinical models
  - Breast cancer (EMT6)
  - Kidney cancer (RENCA)
  - Lung cancer (LLC1)

- Increased survival in EMT6 model

Benchmark

- MRx0518 outperforms bifidobacterium – reported to have anti-tumour effects (Sivan et al. Science 2015)
DISCOVERING EVOLVED FUNCTION OF MRX0518

• Known preclinical efficacy in industry standard models
• MRx0518 induces characteristic immuno-stimulatory gene expression profile in IECs
  • Induction of IL-8, TNF-α, CXCL1, CXCL2, CXCL10 and others
  • Profile associated with TLR-5 pathway stimulation
• MRx0518 is a flagellated bacterium expressing flaA
• Identified by 4D as target for detailed investigation
CLARIFYING THE FLAGELLIN HYPOTHESIS

TLR-5 response: MRx0518
- Both live and heat killed
- CFS induces highest levels of activity
- MRx0518 sheds flagellin

TLR-5 response: MRx0518 vs library strain
- Both flagellated and express flaA
- DSM strain not as effective as MRx0518
-Benchmarked against salmonella flagellin (FLA-ST)
• Developed a gene disruption strategy - created insertion mutant, MRx0518 flaA-

• Comparison to MRx0518 shows MRx0518 flaA- stimulation of TLR5 receptors limited
Developed expression and purification of recombinant flagella

Dose-responsive effects on TLR-5 activation

Differential activity with MRx0518 and library flagella

MRx0518 flagellin more potent than reference strain flagellin
Conclusions
FUNCTIONALITY DRIVES DEVELOPMENT

Conclusions

35 Patent families

206 Granted patents

363 Patent applications
## DEVELOPING SCIENCE, DELIVERING THERAPIES

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<thead>
<tr>
<th>Research</th>
<th>Proprietary platform</th>
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<tr>
<td></td>
<td>Focus on functionality + mechanism</td>
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<tr>
<td></td>
<td>Highly productive</td>
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<tr>
<td>Development + Manufacturing</td>
<td>Glass to stainless steel in-house</td>
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<td>Stable, repeatable processes</td>
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<td>GMP certified</td>
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<tr>
<td>Clinical</td>
<td>Phase Ib completed in IBS patients</td>
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<td></td>
<td>Phase Ib dosing completed in pCD</td>
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<td></td>
<td>More clinical studies planned for 2018</td>
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