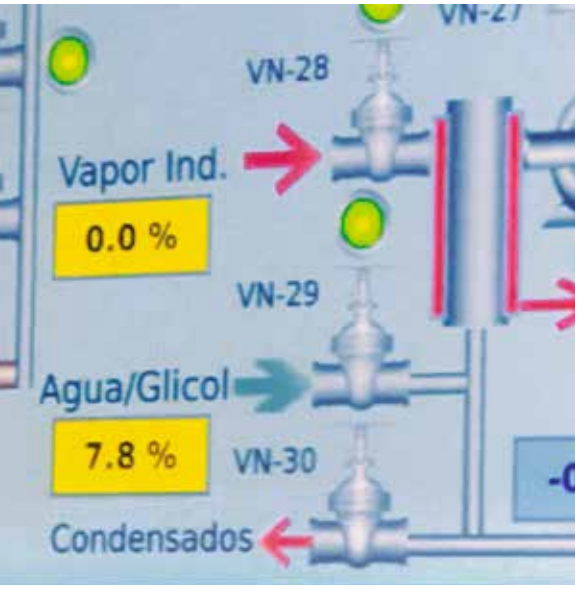
4D pharma plc

A world leader in an emerging field

4D pharma plc Interim Report 2018



We are pioneers in harnessing bacteria as a novel and revolutionary class of medicines:

Live Biotherapeutics

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4dpharmaplc.com

Highlights

Financial highlights

- Net assets as at 30 June 2018 of £58.7 million (30 June 2017: £75.3 million and 31 December 2017: £69.8 million)
- Cash and cash equivalents and short-term deposits at 30 June 2018 of £36.6 million (30 June 2017: £59.8 million and 31 December 2017: £50.0 million)
- Loss attributable to the owners of the parent undertaking for the six months ended 30 June 2018 of £11.3 million (30 June 2017: £11.3 million* and 31 December 2017: £19.4 million*)
- Research and development expenditure for the six months ended 30 June 2018 of £11.8 million (30 June 2017: £8.3 million and 31 December 2017: £16.9 million)

Operational and clinical highlights

- Entering into clinical collaboration agreement with subsidiary of MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA) to conduct a clinical trial evaluating the combination of KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by MSD, and 4D's Live Biotherapeutic candidate MRx0518 in patients with solid tumours; the phase I study will evaluate safety, tolerability and preliminary clinical benefit of the combination of KEYTRUDA® with MRx0518 in patients who progressed on prior PD-1 inhibitor therapy with renal, bladder, melanoma and non-small cell lung cancer
- Clearance by the Medicines and Healthcare Products Regulatory Agency ("MHRA") of the Clinical Trial Application for MRx0518, the first Live Biotherapeutic trial in cancer; the first-in-human, two-part phase Ib study will evaluate the safety, tolerability and anti-tumour immuno-modulatory effects of MRx0518 in patients with multiple solid tumour types
- Clearance by the US Food and Drug Administration ("FDA") of an Investigational New Drug Application for Blautix, the Group's Live Biotherapeutic for the treatment of Irritable Bowel Syndrome ("IBS"); the double-blind, placebo-controlled multicentre phase II study will evaluate the efficacy and safety of Blautix in patients with IBS with constipation ("IBS-C") and IBS with diarrhoea ("IBS-D")
- Clearance by the MHRA and the Health Products Regulatory Authority ("HPRA") to commence the phase II study of Blautix at sites in the UK and Ireland

Since the period end

- Positive top-line results for the Phase Ib study of the Company's Live Biotherapeutic Thetanix in paediatric patients with Crohn's disease; achieving the primary objective of demonstrating that Thetanix was well tolerated with a good safety profile

* Note: this includes a £3.5 million non-recurring charge in relation to the successful completion of the first milestone for 4D Pharma Cork Limited.

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Chairman and Chief Executive Officer's Joint Review

David Norwood, Non-Executive Chairman, and Duncan Peyton, Chief Executive Officer

The microbiome

Whilst 4D is founded on science, innovation and forward thinking, it is history that tells us the most.

The work of von Behring and the development of serum therapy evolved through decades of research into the multi-billion dollar industry of antibody technology. The approval of Epogen in 1989 is another example, beginning in the 17th century with the first blood transfusions in animals that eventually led to the development of Epogen, one of the first drugs to come out of the biotech industry. Both the development of antibodies and Epogen show us that from a complex source (whether this be blood or serum), through scientific endeavour, the focus ultimately ends on functional singularity.

At 4D we believe the development of Live Biotherapeutics is another example of form following function. From the initial reports of faecal matter used in the fourth century to treat food poisoning and diarrhoea, through the development and use of faecal transplants to treat clostridium difficile infection in the 1950s, we are now seeing the first Live Biotherapeutics entering the clinic. However, whereas early Chinese medicine and faecal transplants primarily treated gastrointestinal issues, the Live Biotherapeutics developed by 4D not only treat disease of the gut, but also address the major challenges of cancer, asthma and autoimmune conditions.

Today, rather than form following function, development of new drugs is arguably restricted by the common tools available (i.e. small molecules, proteins and antibodies), and could be considered function following form. Furthermore, drug development is targeted towards a single "validated" target, despite the knowledge that disease pathways do not operate in isolation.

Considering this, it is perhaps no surprise that drugs have significant side effects, and that not all drugs are effective in all patients.

At the level of complex organisms, functionality exists at different levels (organs, tissues and cells), with cells being the simplest unit of independent functionality. Considering more recent history, if the functionality of a single cell can be harnessed in context (i.e. in the state in which it exists naturally), for example with Chimeric Antigen Receptor (CAR-T) or stem cell transplants, the effects are remarkable.

Within the microbiome, a single strain is the simplest cellular unit of functionality, and the microbiome is now understood to have significant functionality relevant to human health.

It is this potential that 4D is seeking: form following function, single strains impacting known disease pathways.

Working with pharma

As more research is done within the field of the microbiome and more papers are published, whether by third parties or those more recently published by the 4D research teams, the stronger the interest grows in the microbiome from the pharmaceutical industry.

The pharmaceutical industry is actively seeking out new innovation, not only in new therapeutics, but also in ways to enhance their existing therapies.

An example of this innovation is the clinical collaboration agreement 4D announced in early June, with a subsidiary of MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA).

This trial will evaluate MRx0518, 4D's lead oncology programme, which has shown therapeutic potential in a variety of tumour types in pre-clinical models and has the potential for synergy in combination with checkpoint inhibitor therapies. The phase I study will evaluate safety, tolerability and preliminary clinical benefit of the combination of KEYTRUDA® with MRx0518 in patients who progressed on prior PD-1 inhibitor therapy with renal, bladder, melanoma and non-small cell lung cancer.

Working within a developing regulatory and clinical environment

The microbiome and Live Biotherapeutics is an emerging field, and as such the regulations are evolving.

The US Food and Drug Administration ("FDA") issued a guidance document in 2016 relating to early stage clinical development of Live Biotherapeutic products. Following on from this, the European Pharmacopoeia has adopted three new quality standards for Live Biotherapeutics for human use in April 2018, with the new texts becoming effective in April 2019. 4D contributed to the development of these quality standards, acting as the UK's representative on the working party that developed the standards.

Throughout regulatory discussions relating to the development of 4D's own products, the focus has primarily been on the safety of patients, but also on developing the thinking surrounding Live Biotherapeutics through rigorous scientific debate. This interaction has led to 4D conducting phase I trials in patients as opposed to healthy subjects, not only demonstrating the potential to develop safer drugs, but also granting us an insight, albeit at a low level, into what we may expect to see in patient population earlier than under traditional development timelines.

Chairman and Chief Executive Officer's Joint Review

continued

David Norwood, Non-Executive Chairman, and Duncan Peyton, Chief Executive Officer

Working within a developing regulatory and clinical environment continued

Notwithstanding that our trials to date have been in patients, 4D is now preparing to expand these trials to generate data that is both significant and statistically relevant to further demonstrate the potential in the microbiome. An example of this is our phase II study in Irritable Bowel Syndrome ("IBS"), a double-blind, placebo-controlled multicentre trial currently being conducted with 500 patients across sites in Europe and the United States. As previously announced, this is the largest trial being conducted with a Live Biotherapeutic which, if successful, we believe will be sufficient to demonstrate efficacy and bring more understanding to the development of Live Biotherapeutics.

Developing a scientific viewpoint/standing

At 4D the bedrock of our business is research; only if 4D continues to build world-leading research will we ultimately succeed.

Whilst we continuously push our programmes through development, the innovative work of our scientific teams continues. One measure of success of our research is the development of our intellectual property estate and 4D continues to lead the field. We now have 355 granted patents across 46 patent families. As our teams uncover new bacteria that are therapeutically relevant, and unpick the mechanism of action or develop novel production techniques, the intellectual property estate will continue to grow in size and value.

Having secured a class leading patent position, our research teams are able to lead the debate on the role of the microbiome and development of Live Biotherapeutics.

Over the last six months the research teams have presented at key microbiome conferences and published papers on some of their findings with immediate relevance to our clinical programmes, such as the potential of the microbiome to serve as novel therapeutic inhibitors of the human enzyme histone deacetylase ("HDAC"), which could lead to new programmes in cancer or neurodegeneration. As we continue our world-leading research, and build our patent portfolio, we will continue to publish and discuss our work.

Conclusion

At 4D pharma we face the challenge of bringing a new blockbuster drug, in a new therapeutic class, to transform patient lives.

We can only continue to meet this challenge if we focus on the core principles of developing science and delivering therapies.

David Norwood
Non-Executive Chairman

Duncan Peyton
Chief Executive Officer
27 September 2018

Group Statement of Total Comprehensive Income

For the six months to 30 June 2018

	Notes	**Unaudited six months ended 30 June 2018 £000**	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Research and development costs		**(11,829)**	(8,305)	(16,911)
Administrative expenses		**(1,969)**	(1,047)	(3,529)
Foreign currency gains/(losses)		**605**	(439)	(431)
Operating loss before non-recurring cost		**(13,193)**	(9,791)	(20,871)
Non-recurring costs		**—**	(3,474)	(3,474)
Operating loss after non-recurring cost		**(13,193)**	(13,265)	(24,345)
Finance income		**190**	287	482
Finance expense		**(167)**	(17)	(123)
Loss before taxation		**(13,170)**	(12,995)	(23,986)
Taxation	3	**2,520**	1,179	3,541
Loss for the year		**(10,650)**	(11,816)	(20,445)
Other comprehensive income				
Exchange differences on translating foreign operations		**(652)**	566	1,057
Loss for the year and total comprehensive income for the year		**(11,302)**	(11,250)	(19,388)
Loss per share				
Basic and diluted for the year	4	**(16.26)p**	(18.22)p	(31.41)p

Group Statement of Financial Position

At 30 June 2018

	Notes	**At 30 June 2018 £000**	At 30 June 2017 £000	At 31 December 2017 £000
Assets				
Non-current assets				
Property, plant and equipment		**5,001**	4,782	5,211
Intangible assets		**14,515**	14,604	14,674
Taxation receivables		**84**	23	56
		19,600	19,409	19,941
Current assets				
Inventories		**262**	194	253
Trade and other receivables		**2,193**	2,813	3,238
Taxation receivables		**6,442**	3,892	4,308
Short-term investments and cash on deposit		**15,151**	10,000	38,133
Cash and cash equivalents		**21,405**	49,772	11,865
		45,453	66,671	57,797
Total assets		**65,053**	86,080	77,738
Liabilities				
Current liabilities				
Trade and other payables		**3,251**	7,899	4,982
		3,251	7,899	4,982
Non-current liabilities				
Deferred tax		**965**	963	965
Other payables	5	**2,165**	1,875	2,005
		3,130	2,838	2,970
Total liabilities		**6,381**	10,737	7,952
Net assets		**58,672**	75,343	69,786
Capital and reserves				
Share capital		**164**	162	164
Share premium account		**108,296**	105,909	108,296
Merger reserve		**958**	958	958
Translation reserve		**16**	177	668
Other reserve		**(864)**	(864)	(864)
Share-based payments reserve		**628**	248	440
Retained earnings		**(50,526)**	(31,247)	(39,876)
Total equity		**58,672**	75,343	69,786

Approved by the Board and authorised for issue on 27 September 2018.

Duncan Peyton
Director
27 September 2018

Group Statement of Changes in Equity

For the six months to 30 June 2018

	Share capital £000	Share premium £000	Merger reserve £000	Translation reserve £000	Other reserve £000	Share-based payment reserve £000	Retained earnings £000	Total £000
At 1 January 2017	162	105,909	958	(389)	(864)	138	(19,431)	86,483
Loss and total comprehensive income for the period	—	—	—	—	—	—	(11,816)	(11,816)
Foreign currency gains/losses arising on consolidation of subsidiaries	—	—	—	566	—	—	—	566
Issue of share-based compensation	—	—	—	—	—	110	—	110
At 30 June 2017	162	105,909	958	177	(864)	248	(31,247)	75,343
Issue of share capital (net of expenses)	2	2,387	—	—	—	—	—	2,389
Total transactions with owners recognised in equity for the year	2	2,387	—	—	—	—	—	2,389
Loss and total comprehensive income for the period	—	—	—	—	—	—	(8,629)	(8,629)
Foreign currency gains/losses arising on consolidation of subsidiaries	—	—	—	491	—	—	—	491
Issue of share-based compensation	—	—	—	—	—	192	—	192
At 31 December 2017	164	108,296	958	668	(864)	440	(39,876)	69,786
Loss and total comprehensive income for the period	—	—	—	—	—	—	(10,650)	(10,650)
Foreign currency gains/losses arising on consolidation of subsidiaries	—	—	—	(652)	—	—	—	(652)
Issue of share-based compensation	—	—	—	—	—	188	—	188
At 30 June 2018	**164**	**108,296**	**958**	**16**	**(864)**	**628**	**(50,526)**	**58,672**

Group Cash Flow Statement

For the six months to 30 June 2018

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Loss after taxation	**(10,650)**	(11,816)	(20,445)
Adjustments for:			
Depreciation of property, plant and equipment	**443**	324	730
Amortisation of intangible assets	**148**	117	252
Loss on disposal of property, plant and equipment	**—**	78	79
Finance income	**(190)**	(287)	(482)
Finance expense	**167**	17	123
Non-recurring contingent consideration	**—**	3,474	3,474
Share-based compensation	**188**	110	302
Cash flows from operations before movements in working capital	**(9,894)**	(7,983)	(15,967)
Changes in working capital:			
(Increase)/decrease in inventories	**(9)**	44	(15)
Decrease/(increase) in trade and other receivables	**393**	(23)	(588)
Increase in taxation receivables	**(2,164)**	(578)	(1,009)
(Decrease)/increase in trade and other payables	**(1,614)**	519	389
Cash outflow from operating activities	**(13,288)**	(8,021)	(17,190)
Cash flows from investing activities			
Purchases of property, plant and equipment	**(259)**	(1,078)	(1,885)
Purchase of software and other intangibles	**(4)**	(43)	(194)
Interest received	**115**	147	509
Monies placed on/(drawn from) deposit	**22,982**	30,111	1,978
Net cash outflow from investing activities	**22,834**	29,137	408
Cash flows from financing activities			
Hire purchase payments	**(6)**	(5)	(14)
Net cash inflow from financing activities	**(6)**	(5)	(14)
Increase/(decrease) in cash and cash equivalents	**9,540**	21,111	(16,796)
Cash and cash equivalents at the start of the year	**11,865**	28,661	28,661
Cash and cash equivalents at the end of the year	**21,405**	49,772	11,865

Notes to the Interim Financial Report

For the six months ended 30 June 2018

1. Basis of preparation

The Group's half-yearly financial information, which is unaudited, consolidates the results of 4D pharma plc and its subsidiary undertakings up to 30 June 2018. The Group's accounting reference date is 31 December. 4D pharma plc's shares are quoted on the AIM Market of the London Stock Exchange ("AIM").

The Company is a public limited liability company incorporated and domiciled in the UK. The consolidated financial information is presented in round thousands of Pounds Sterling (£'000).

The financial information for the six months ended 30 June 2018 and 30 June 2017 is unaudited.

Full audited financial statements of the Group in respect of the period ended 31 December 2017, which received an unqualified audit opinion and did not contain a statement under section 498(2) or (3) of the Companies Act 2006, have been delivered to the Registrar of Companies.

The accounting policies used in the preparation of the financial information for the six months ended 30 June 2018 are in accordance with the recognition and measurement criteria of International Financial Reporting Standards as adopted by the European Union ("IFRS") and are consistent with those which will be adopted in the annual financial statements for the year ending 31 December 2018.

Whilst the financial information included has been prepared in accordance with the recognition and measurement criteria of IFRS, the financial information does not contain sufficient information to comply with IFRS.

4D pharma plc has not applied IAS 34 Interim Financial Reporting, which is not mandatory for UK AIM listed groups, in the preparation of this interim financial report.

2. Going concern

Having prepared management forecasts and made appropriate enquiries, the Directors are satisfied that the Group has adequate resources for the foreseeable future as the Group is at the start-up stage of its business lifecycle. Accordingly they have continued to adopt the going concern basis in preparing the financial information.

3. Taxation

The tax credit is made up as follows:

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Current income tax			
Total current income tax	**2,520**	1,169	3,557
Adjustment in respect of prior years	**—**	10	(16)
Total income tax credit recognised in the year	**2,520**	1,179	3,541

4. Loss per share

(a) Basic and diluted

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Loss for the year attributable to equity shareholders	**(10,650)**	(11,816)	(20,445)
Weighted average number of shares:			
Ordinary shares in issue	**65,493,842**	64,858,150	65,084,561
Basic loss per share (pence)	**(16.26)p**	(18.22)p	(31.41)p

The basic and diluted loss per share are the same as the effect of share options is anti-dilutive.

Notes to the Interim Financial Report *continued*

For the six months ended 30 June 2018

4. Loss per share continued

(b) Adjusted

Adjusted loss per share is calculated after adjusting for the effect of non-recurring expenses in relation to the reassessment of the contingent liability.

Reconciliation of adjusted loss after tax:

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Reported loss after tax	**(10,650)**	(11,816)	(20,445)
Non-recurring costs	**—**	3,474	3,474
Adjusted loss after tax	**(10,650)**	(8,342)	(16,971)
Adjusted basic loss per share (pence)	**(16.26)p**	(12.86)p	(26.08)p

5. Other payables

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Non-current payables			
Contingent consideration (see below and note 6)	**2,144**	1,875	1,979
Hire purchase and finance leases	**21**	—	26
	2,165	1,875	2,005

Contingent consideration

The non-current contingent consideration is made up as follows:

	Unaudited six months ended 30 June 2018 £000	Unaudited six months ended 30 June 2017 £000	Audited year to 31 December 2017 £000
Brought forward	**1,979**	774	774
Reassessment of contingent consideration to be satisfied in shares	**—**	4,395	4,395
Discounting of estimated future cash flows	**—**	(921)	(921)
Part settlement of contingent consideration in shares	**—**	—	(2,389)
Unwinding of discount	**165**	16	120
	2,144	4,264	1,979
Analysed as follows:			
Within one year	**—**	2,389	—
More than one year	**2,144**	1,875	1,979
	2,144	4,264	1,979

Notes to the Interim Financial Report *continued*

For the six months ended 30 June 2018

6. Contingent consideration

On 23 August 2017 635,692 new ordinary shares were issued. The allotment represents contingent consideration in respect of the acquisition of the entire issued share capital of 4D Pharma Cork Limited (formerly Tucana Health Limited), which completed in February 2016, and follows the achievement of 4D Pharma Cork's initial milestone.

The milestone achieved reflects the technical validation of the MicroDx diagnostic platform, enabling the stratification of IBS patients. MicroDx has been designed to diagnose, stratify and monitor the treatment of patients based on their gut microbiome, the bacteria which colonise the human gastrointestinal tract.

The new 4D ordinary shares have been allotted for an aggregate value of €2.6 million (at £3.7575 per 4D share, being the average mid-market price of a 4D share for the five business days immediately preceding the date of allotment) and were admitted on 31 August 2017.

Produced by
designportfolio

pharma plc

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