



Interim results for the period ended 30 June 2015

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4d Pharma PLC

29 September 2015

("4D" or "the Company")

Interim results for the six months ended 30 June 2015

4D pharma plc (AIM: DDDD), a pharmaceutical company focussing on the development of live biotherapeutics targeting important new therapeutic areas, is pleased to announce the interim results for the Company and its subsidiaries (together "the Group") for the six months ended 30 June 2015.

Financial highlights

- Net assets as at 30 June 2015 of £66.6m.
- Cash and cash equivalents and short term deposits at 30 June 2015 of £61.5m.
- Loss attributable to the owners of the parent undertaking for the six months ending 30 June 2015 of £4.1m.

Corporate highlights

- Further placing in February 2015 of 8,475,610 new ordinary shares at 410 pence per share, raising £34.3m (net of expenses).
- Acquisition in March 2015 of remaining minority interests in 4D pharma Research Limited (formerly GT Biologics Limited) to increase the Company's stake to 100%.

Other highlights

- Successful development the Company's discovery platform MicroRx, expanding its library to over 2,000 bacteria, targeting discovery of candidates across multiple disease sectors.
- Identification, via the MicroRx platform, of bacteria demonstrating therapeutically relevant effects in pre-clinical models of rheumatoid arthritis and severe asthma.

Since the period end

- Identification, via the MicroRx platform, of bacteria demonstrating therapeutically relevant effects in an industry standard model of multiple sclerosis.
- Entry into a €4.8 million four-year collaboration project with the APC Microbiome Institute at University College Cork; researching the potential applications of live biotherapeutics in relation to Autism Spectrum Disorders and associated disorders of the central nervous system.
- Commencement of phase 1 clinical trials in respect of Blautix™, a live biotherapeutic being developed for the treatment of irritable bowel syndrome.

Chairman's statement

Dave Norwood, Chairman of 4D commented: "The period has seen significant progress towards bringing a new class of therapeutics to market, with the development of the MicroRx discovery platform which has successfully identified therapeutically relevant bacteria in important new disease areas. The period has also seen the second successful institutional placing within the Company's first year post IPO; demonstrating shareholder support for our vision for 4D. With the Company's first programme now having entered into patient trials, and further success for MicroRx, we believe this to be a hugely exciting period for the Company."

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For further information please visit: www.4dpharmapl.com.

Chairman's and Chief Executive Officer's Joint Review

Overview

4D pharma is a pharmaceutical company focusing on the development of live biotherapeutics.

4D pharma has two programmes entering clinical trials, with a further 11 research and development programmes in diseases such as multiple sclerosis, asthma and irritable bowel disease. With this clinical progress and breadth of pipeline from MicroRx, 4D's proprietary platform, 4D is a world leader in this new and emerging field.

Live biotherapeutics are a new class of drugs, defined by the FDA as a biological product that contains live organisms (such as bacteria), applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is not a vaccine.

In recent years, there have been rapid and significant scientific advances in our understanding of the ways that bacteria interact with the human body. Through co-existing with us as natural inhabitants of the gut, they have evolved the capability to influence the development and maintenance of key biological pathways such as the immune system. As such, they have significant potential as precisely controlled therapeutics, offering an alternative to traditional small molecule or biologic drugs.

In addition to possible therapeutic effects, a further advantage is that, due to their inherent nature, live biotherapeutics offer the potential for greatly reduced side effects relative to traditional therapeutics. 4D has taken that understanding and applied it to the

development of live biotherapeutic products in a regulated environment.

Further, as the site for delivery is the gut, all the products being developed by 4D are delivered by oral capsules, removing the costs and issues associated with the injection or infusion of complex biologics, and potentially increasing patient adherence.

4D has developed a proprietary platform, MicroRx, which allows the Company to rationally identify bacteria that are shown to have a significant biological effect pre-clinically, and rapidly develop these bacteria into candidates to take into clinical trials.

Over the last six months we have focussed our efforts on development and regulatory protocols to take our first programmes into man, as well as expanding our research and development effort to identify new candidates.

MicroRx

The MicroRx platform is an engine allowing 4D to discover bacteria with potential therapeutic effects in target disease areas. It was specifically developed by 4D for this purpose and is proprietary to 4D. We believe the MicroRx platform gives 4D a unique advantage to develop live biotherapeutics across multiple disease sectors, including autoimmune, CNS and cancer, not just those historically associated with the gut.

To date, from our expanding library of over 2,000 bacteria, MicroRx has been targeted towards the discovery of candidates in multiple sclerosis, asthma and rheumatoid arthritis. These programmes have shown significant promise, and provided us with a greater insight into the importance of the microbiome and the potential impact of live biotherapeutics.

Our work has shown the importance of the microbiome and the potential of live biotherapeutics with the discovery of potentially novel pathways in the treatment of asthma. We have also shown, pre-clinically, the prevention of the development of multiple sclerosis with demonstrably clear efficacy.

We are investigating clinical study designs to demonstrate early proof of concept, and developing regulatory strategies to get products to patients as soon as possible, based on inherent safety, understanding mechanism of action and disease modifying effects.

Blautix™ - Irritable Bowel Syndrome

Irritable bowel syndrome ("IBS") is a functional bowel disorder characterised by discomfort, pain and changes in bowel habits. Symptoms can be mild, moderate or severe. Mild symptoms, which occur infrequently, can sometimes interfere with normal daily functioning. Moderate symptoms are more intense, occur more frequently, and often interfere with daily functioning. Severe symptoms chronically interfere with daily functioning. It is estimated that 10-15% of the population have IBS, with only 30-35% of patients seeking medical attention, the majority of whom have persistent symptoms. There are currently few approved treatment options, all of which focus on the modulation of symptoms.

Blautix™ is a live biotherapeutic being developed as a treatment for IBS. In the period to 30 June 2015 preparations were underway for the first in man clinical study. This subsequently commenced in August. The study is primarily concerned with evaluating safety and tolerability of the product. Additionally, biomarkers relevant to clinical effect will be assessed in healthy volunteers and symptomatic IBS individuals.

Thetanix™ - Paediatric Crohn's

Thetanix™ is a live biotherapeutic for the treatment of Paediatric Crohn's ("PCD").

PCD is a chronic inflammatory bowel disease that causes inflammation, or swelling, across the lining of the digestive tract. Crohn's disease most often affects the end of the small intestine but can happen anywhere along the digestive tract from mouth to anus. In addition to gastro intestinal symptoms (diarrhoea, rectal bleeding, abdominal pain), children with PCD often experience growth failure, malnutrition, pubertal delay and bone demineralisation. Approximately 20% of patients with Crohn's disease present when they are younger than 20 years and it is estimated that there are around 41,000 children in the United States with PCD.

Thetanix™ has received orphan drug designation from the FDA and is expected to enter clinical trials before the end of 2015. Over the last six months we have worked to optimise production processes for the product, and to finalise clinical protocols. Due to the inherent characteristics of Thetanix™, it is intended that the trial will be conducted in patients, and although concerned primarily with safety and tolerability, biomarkers relevant to clinical effect will be assessed.

Rosburix™ - Paediatric Ulcerative Colitis

Rosburix is being developed for the treatment of Paediatric Ulcerative Colitis ("PUC") and was granted orphan drug designation by the FDA in August 2014.

PUC is an inflammation, or painful swelling, of the lining of the large intestine or colon. The inflammation can lead to sores and ulcers which can bleed, produce pus and cause pain. Although some patients with PUC do show periods of remission, PUC is a long term condition, with patients requiring management throughout life. Despite a number of approved therapeutic options for treatment, surgical removal of the colon is still required in many cases, and in the United States it is estimated that 8% of paediatric patients undergo colectomy at 1 year, 15% at 3 years and 20% at 5 years following diagnosis.

It is estimated that in the United States 28 of every 100,000 children are affected with PUC, and it is one of the most common gastrointestinal conditions managed by gastroenterologists there. There is a clear, unmet medical need for better therapeutic treatments for children suffering from PUC.

Rosburix™ is expected to enter clinical trials in 2016.

Additional pipeline programmes

The period to 30 June 2015 saw the Group make significant progress in identifying potential live biotherapeutic treatments for a range of important inflammatory and autoimmune diseases using its MicroRx platform. Having already successfully taken one programme into clinical trials, the Group aims to apply the same methodologies to these new programmes, in order that they can enter clinical development and be of potential benefit to patients in as short a time as possible.

- **MRx 751 and MRx 433 - Severe Asthma**

Severe asthma is a specific type of asthma requiring specialist care and support. The symptoms experienced are much more difficult to control; for example a severe asthma patient may not respond to steroids, more usually being on combination therapies; severe asthma cases are usually managed at specialist centres.

Incidence is around 5-8% of asthma sufferers, and the estimated prevalence population within the United States and EU3 (i.e. together France, Germany and the United Kingdom) was 3,000,000 in 2014.

MRx 751 and MRx 433 are being developed as separate programmes to treat different forms of severe asthma. The preclinical work has shown that each of the bacteria has distinct and potentially novel mechanisms of action. Work is now progressing on development of drug product and potential clinical protocols.

- **MRx 675 - Multiple Sclerosis**

MRx 675 is being developed for multiple sclerosis ("MS").

MS affects nerves in the brain and spinal cord. In MS the protective layer, called myelin, becomes damaged, disrupting the transfer of nerve signals and causing a wide range of symptoms, including problems with muscle movement, balance and vision. The estimated prevalence of MS with the United States and EU3 is 750,000 with the incidence estimated to be about 2-5% of the prevalent population. However, with increased awareness and improved diagnosis it is believed the incidence is increasing.

MRx 675 has shown high levels of efficacy in a pre-clinical model of MS, with a potentially novel mechanism of action.

- **MRx 830 - Rheumatoid Arthritis**

MRx 830 is being developed for rheumatoid arthritis.

Rheumatoid arthritis ("RA") is a long-term condition that causes pain, swelling and stiffness in the joints.

As a chronic, progressive condition, there may be periods where symptoms become worse, known as a flare-up or flare. A flare can be

difficult to predict, but with treatment it is possible to decrease the number of flares and minimise or prevent long-term damage to the joints.

RA is the most prevalent of the inflammatory rheumatic diseases, with estimated incidence rates of up to 8%, with 3,200,000 RA patients across the United States and EU3.

MRx 830 has shown high levels of efficacy in a pre-clinical model of RA and is undergoing further evaluation before entering pre-clinical development.

Financial results

The consolidated loss on ordinary activities attributable to the owners of the parent undertaking of £4.1m for the six months ending 30 June 2015 is in line with expectations and includes all of the ordinary activities of 4D pharma Research Limited (formerly GT Biologics Limited) following the increase in 4D's ownership to 100% in March 2015.

The Company has further strengthened its balance sheet raising £34.3m (net of expenses) in February 2015.

David Norwood

Chairman

28 September 2015

Duncan Peyton

Chief Executive Officer

28 September 2015

Consolidated Statement of Comprehensive Income

For the six months ended 30 June 2015

Note:

	Unaudited period from 10 January 2014 to 30 June 2014	Audited period from 10 January 2014 to 31 December
Unaudited six months ended 30	Unaudited period from 10 January 2014 to 30 June 2014	Audited period from 10 January 2014 to 31 December

	June 2015	(restated)	2014
	£'000s	£'000s	£'000s
Revenue	-	117	-
Operating expenses	(4,466)	(684)	(3,476)
Operating loss	(4,466)	(567)	(3,476)
Finance income	191	25	92
Finance expense	-	(5)	(5)
Share of losses in associate undertaking	2 -	(379)	(379)
Gain on measurement of equity interest to fair value on acquisition of a subsidiary	2 -	1,388	1,388
(Loss)/profit before tax	(4,275)	462	(2,380)
Taxation	-	-	-
(Loss)/profit for the period and total comprehensive income from the period	(4,275)	462	(2,380)
(Loss)/profit for the period and total comprehensive income from the			

period**attributable to:**

Owners of the
parent undertaking
Non-controlling
interests

(4,091)	499	(2,021)
(184)	(37)	(359)

**(Loss)/profit for
the period and
total
comprehensive
income from the
period**

(4,275)	462	(2,380)
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(Loss)/earnings**per share:**

Basic & diluted
(loss)/earnings for
the period

4	<u>(6.93)p</u>	<u>1.54p</u>	<u>(4.81)p</u>
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**Consolidated Statement of Changes in Equity
For the six months ended 30 June 2015**

	Share capital £'000	Share premium £'000	Merger reserve £'000	Other reserve £'000	Retained earnings £'000	Total reserves £'000	Non Controlling interest £'000	Total equity £'000
At 10 January 2014	-	-	-	-	-	-	-	-
Issue of share capital (net of expenses)	93	16,279	958	-	-	17,330	-	17,331
Total transactions with owners recognised in equity	93	16,279	958	-	-	17,330	-	17,331
Profit and comprehensive income for the period	-	-	-	-	499	499	(37)	462
Non-controlling interest share of the	-	-	-	-	-	-	81	81

group on acquisition At 30 June 2014	93	16,279	958	-	499	17,829	44	17,873
Issue of share capital (net of expenses)	37	21,980	-	-	-	22,017	-	22,017
Total transactions with owners recognised in equity	130	38,259	958	-	499	39,846	44	39,890
(Loss) and comprehensive income for the period	-	-	-	-	(2,520)	(2,520)	(322)	(2,842)
At 31 December 2014	130	38,259	958	-	(2,021)	37,326	(278)	37,048
Issue of share capital (net of expenses)	21	34,242	-	-	-	34,263	-	34,263
Acquisition of minority interest	-	-	-	(320)	(544)	(864)	462	(402)
Total transactions with owners recognised in equity	151	72,501	958	(320)	(2,565)	70,725	184	70,909
(Loss) and comprehensive income for the period	-	-	-	-	(4,091)	(4,091)	(184)	(4,275)
At 30 June 2015	151	72,501	958	(320)	(6,656)	66,634	-	66,634

Consolidated Statement of Financial Position
As at 30 June 2015

	Unaudited six months ended 30 June 2015	Unaudited period from 10 January 2014 to 30 June 2014 (restated)	Audited period from 10 January 2014 to 31 December 2014
	£'000s	£'000s	£'000s
Assets			
Non-current assets			
Property, plant and equipment	584	215	417
Intangible assets	6,213	4,253	6,266
	6,797	4,468	6,683

Current assets

Inventories	98	-	115
Trade and other receivables	427	250	590
Short-term investments and cash on deposit	42,128	2,000	3,007
Cash and cash equivalents	19,348	12,100	28,823
	62,001	14,350	32,535

Total assets

	68,798	18,818	39,218
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Liabilities**Current liabilities**

Trade and other payables	1,779	560	1,785
	1,779	560	1,785

Non-current liabilities

Deferred tax	385	385	385
Total liabilities	2,164	945	2,170

Net assets

	66,634	17,873	37,048
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Capital and reserves

Share capital	151	93	130
Share premium	72,501	17,237	38,259
Merger reserve	958	-	958
Other reserve	(320)	-	-
Retained earnings	(6,656)	499	(2,021)
	66,634	17,829	37,326

Non-controlling interest	-	44	(278)
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Total equity	66,634	17,873	37,048
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Approved by the Board and authorised for issue on 28 September 2015.

Duncan Peyton

Director

Consolidated Cash Flow Statement
For the six months ended 30 June 2015

	Unaudited six months ended 30 June 2015	Unaudited period from 10 January 2014 to 30 June 2014 (restated)	Audited period from 10 January 2014 to 31 December 2014
	£'000s	£'000s	£'000s
Cash flows from operating activities			
Results before taxation	(4,275)	462	(2,380)
Adjustments for:			
Depreciation of property, plant and equipment	59	28	65
Amortisation of intangible assets	53	-	49
Finance income	(191)	(25)	(92)
Finance expense	-	5	5
Gain on remeasurement of existing interest on acquisition of subsidiary to fair value	-	(1,388)	(1,388)
Share of losses in associated undertaking	-	379	379
Cash flows from operations before movements in working capital	(4,354)	(539)	(3,362)
Changes in working capital:			
Decrease/(increase) in inventories	17	-	(115)
Decrease/(increase) in trade and other receivables	163	(135)	(474)
(Decrease)/increase in trade and other payables	(6)	(16)	133
Cash outflow from operating activities	(4,180)	(690)	(3,818)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(226)	(24)	(264)
Loan advanced	-	(1,076)	(1,076)
Acquisition of subsidiaries net of cash acquired	(402)	238	238
Interest received	191	25	92
Monies placed on deposit	(39,121)	(2,000)	(3,007)
Net cash outflow from investing activities	(39,558)	(2,837)	(4,017)
Cash flows from financing activities:			
Proceeds from the issues of ordinary share capital	34,750	16,600	38,100
Expenses on issue of shares	(487)	(468)	(937)
Repayment of loan	-	(500)	(500)
Interest paid	-	(5)	(5)

Net cash inflow from financing activities	34,263	15,627	36,658
(Decrease)/increase in cash and cash equivalents	(9,475)	12,100	28,823
Cash and cash equivalents at the start of period	28,823	-	-
Cash and cash equivalents at the end of the period	19,348	12,100	28,823

Notes to the Interim Financial Report For the six months ended 30 June 2015

1. Basis of preparation

The Group's financial information, which is unaudited, consolidates the results of 4D pharma plc and its subsidiary undertakings up to 30 June 2015. 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 accounting policies used in the preparation of the financial information for the six months ended 30 June 2015 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 2015.

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.

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.

The comparative financial information for the period ended 30 June 2014 has been extracted from the 30 June 2014 financial information and restated as per the comments below. The comparative financial information for the period ended 31 December 2014 has been extracted from the annual financial statements of 4D pharma plc. The financial information for the period ended 30 June 2015, which are not audited, do not comprise statutory accounts within the meaning of section 434 of the Companies Act 2006. The financial information does not therefore include all of the information and disclosures required in the annual financial statements.

Full audited financial statements of the Group in respect of the period ended 31 December 2014, 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.

2. Restatement

The financial information for the period ending 30 June 2014 have been restated to take account of step accounting provisions set out in IFRS 3 Business Combinations. The acquisition of 83.5% of 4D pharma Research Limited (formerly GT Biologics Limited) has been restated to include the separate step accounting provisions of the initial acquisition of 46% of the ordinary share capital in January 2014 and the further acquisition of 37.5% of the ordinary share capital in June 2014. This has resulted in the following amendments:

- Recognition in the consolidated statement of comprehensive income of share of losses in associate of £0.379m.
- Recognition in the consolidated statement of comprehensive income of a gain on measurement of equity interest to fair value on acquisition of a subsidiary of £1.388m. A deferred tax provision of £0.385m was made against this gain.
- An increase in the recognition of goodwill and intellectual property from £2.648m to £4.253m in the consolidated statement of financial position.
- Loss per ordinary share of 1.43p has been restated to earnings per ordinary share of 1.54p.

3. 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 in the start-up stage of its business life cycle. Accordingly they have adopted the going concern basis in preparing the financial information.

4. (Loss)/earnings per ordinary share

	Unaudited six months ended 30 June 2015	Unaudited period from 10 January 2014 to 30 June 2014 (restated)	Audited period from 10 January 2014 to 31 December 2014
	£'000s	£'000s	£'000s
(Loss)/profit attributable to equity holders of the parent	(4,091)	499	(2,021)
Weighted average number of shares:			
Ordinary shares in issue	59,031,215	32,389,453	42,001,850
Basic & diluted (loss)/earnings per share (pence)	(6.93)	1.54	(4.81)

5. Interim financial report

A copy of this interim financial report will be available on the Company's website at www.4dpharmapl.com

This information is provided by RNS
The company news service from the London Stock Exchange

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