# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 6-K

**Report of Foreign Private Issuer**
**Pursuant to Rule 13a-16 or 15d-16**
**under the Securities Exchange Act of 1934**

For the month of **February, 2022**

**Commission File Number: 001-40106**

# 4D pharma plc
*(Translation of Registrant's name into English)*

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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

**Announcement of additional positive data from Part A of the Phase I/II trial of MRx-4DP0004 for the treatment of asthma**

On January 27, 2022, 4D pharma plc issued the press release attached hereto as Exhibit 99.1 and incorporated herein by reference.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**4D pharma plc**

Date: February 2, 2022

*/s/ Duncan Peyton*

Duncan Peyton
Chief Executive Officer

**INDEX TO EXHIBITS**

| Exhibit Number | Exhibit Title |
| --- | --- |
| 99.1 | Press Release, dated January 27, 2022. |

**Exhibit 99.1**

**4D pharma announces additional positive data from Part A of the Phase I/II trial of MRx-4DP0004 for the treatment of asthma**

- Part A of the trial achieved the primary endpoint of safety and tolerability

- Multiple secondary endpoints show positive trends in improving asthma control, supporting progression into Part B of the Phase I/II trial

- Company to host conference call and webcast to discuss results today at 08:00 a.m. ET (1:00 p.m. GMT)

**Leeds, UK, January 27, 2022 – 4D pharma plc (AIM: DDDD, NASDAQ: LBPS)**, a pharmaceutical company leading the development of Live Biotherapeutic products (LBPs), a novel class of drug derived from the microbiome, today announces additional clinical data from Part A of its Phase I/II trial of MRx-4DP0004, an orally-delivered single strain Live Biotherapeutic being developed for the treatment of asthma. The Company previously reported topline safety and efficacy data from Part A, and today announces additional details of these results.

The Phase I/II trial is a multi-center, double-blind, placebo-controlled study in patients with partly controlled asthma taking long-term medication. The primary endpoint of Part A was to evaluate the safety and tolerability of MRx-4DP0004. Secondary endpoints evaluating clinical activity include Asthma Control Questionnaire (ACQ-6), use of short-acting beta agonist (SABA) rescue medication, Asthma Quality of Life Questionnaire (AQLQ), lung function, and exacerbations.

As previously announced, Part A met the primary endpoint and the safety profile of MRx-4DP0004 was comparable to placebo. In addition, MRx-4DP0004 showed activity across multiple secondary endpoints compared to placebo, generating promising preliminary signals of clinical activity which support progression into Part B of the Phase I/II study. Part B is expected to enroll up to 90 patients and will assess clinical efficacy in addition to exploratory immune and microbiome biomarkers.

*"The further clinical results announced today are highly encouraging. Beyond achieving the primary endpoint, we have seen positive trends in multiple secondary endpoints of efficacy that we will be assessing in Part B, including statistical significance at all time points in what will be the primary endpoint in the Part B phase of this trial,"* commented Duncan Peyton, Chief Executive Officer, 4D pharma. *"These results further demonstrate the ability of 4D pharma's MicroRx platform to identify Live Biotherapeutics that are able to drive systemic effects and deliver new treatments to patients in need."*

**MRx-4DP0004 Phase I/II Trial Overview and Results from Part A**

Part A of the Phase I/II clinical trial enrolled 34 patients, randomized 1:1 to receive oral MRx-4DP0004 (N=18) or placebo (N=16) twice daily for 12 weeks, in addition to their usual maintenance therapy of inhaled corticosteroids (ICS) with or without long-acting beta agonist (LABA).

- MRx-4DP0004 achieved the primary endpoint of safety and tolerability in combination with ICS and LABA. 61.1% of patients receiving MRx-4DP0004 experienced any adverse event (AE) compared to 75.0% of patients receiving placebo, of which only two were possibly related to MRx-4DP0004. All AEs were mild or moderate in severity. No serious adverse events (SAEs) related to treatment were reported.

- At all timepoints throughout the treatment period, a significantly greater proportion of MRx-4DP0004 treated patients experienced reductions from baseline in Asthma Control Questionnaire (ACQ-6) score, as compared to placebo. At end of treatment, 83.3% of patients receiving MRx-4DP0004 experienced reductions in ACQ-6 score, compared to 56.3% in the placebo arm. The proportion of patients with reductions in ACQ-6 score at end of treatment will be the primary endpoint for Part B of the Phase I/II trial.

- Moreover, at end of treatment, 50.0% of patients receiving MRx-4DP0004 experienced reductions from baseline in ACQ-6 scores of 0.5 or more, compared to 37.5% in the placebo arm.

- At the end of treatment, 50% of patients receiving MRx-4DP0004 reduced their use of SABA, compared to 18.8% of patients receiving placebo. Overreliance on SABA rescue medication is associated with a greater risk of exacerbations, hospitalizations and mortality, and reduced SABA use is a key indicator of improved asthma control.

- 50.0% of patients receiving MRx-4DP0004 experienced a clinically meaningful increase in Asthma Quality of Life Questionnaire (AQLQ) scores of ≥0.5 at end of treatment, compared to 31.3% receiving placebo.MRx-4DP0004-treated patients' quality of life continued to improve over the treatment period.

- Mean measures of lung function including forced expiratory volume in the first second (FEV1, percentage of predicted), peak expiratory flow (PEF), and ratio of FEV1 to forced vital capacity (FEV1/FVC) for both MRx-4DP0004 and placebo treatment arms generally remained within normal ranges from baseline to end of treatment.

- One of 18 patients (5.6%) randomized to MRx-4DP0004 experienced an asthma exacerbation, compared to two of 16 patients (12.5%) randomized to placebo.

**Conference Call & Webcast Information**

4D pharma will host a conference call and live webcast at 8:00 a.m. ET (1:00 p.m. GMT) today, Thursday January 27, 2022. To access the live webcast, please visit the 'Events' section of the 4D pharma website at www.4dpharmaplc.com. A replay of the webcast and accompanying slides will be available on the 4D pharma website following the event.

**About MRx-4DP0004**

MRx-4DP0004 is an oral, immunomodulatory, single strain Live Biotherapeutic product. 4D pharma has demonstrated the ability of MRx-4DP0004 ability to reduce airway inflammation in a pre-clinical model of severe asthma. This is achieved through a concurrent reduction in both neutrophilic and eosinophilic infiltration and inflammation. MRx-4DP0004 is currently being evaluated in a two-part, randomized, double-blinded, placebo-controlled study evaluating the safety, tolerability and efficacy of MRx-4DP0004 in patients with partly controlled asthma (Clinical Trial identifier: NCT03851250).

**About Asthma**

Asthma is an inflammatory disease of the lungs characterized by recurring symptoms, reversible airflow obstruction, and bronchospasm. Asthma affects 300 million people globally. Between 5-10% of asthma patients have the severe form of the disease, which is refractory to steroid treatment and cannot be controlled with high-intensity treatments and accounts for more than 50% of asthma associated healthcare costs. There is a growing body of evidence linking the gut microbiome to the development of asthma. The global asthma therapeutics market is projected to reach $23.1 billion by 2023.

In severe asthma, airway inflammation can be predominantly eosinophilic, neutrophilic or mixed. Whilst a number of biologics have recently been approved to treat patients with eosinophilic disease, there are currently no approved therapies for patients who present with a neutrophilic phenotype.

**About 4D pharma**

4D pharma is a world leader in the development of Live Biotherapeutics, a novel and emerging class of drugs, defined by the FDA as biological products that contain a live organism, such as a bacterium, that is applicable to the prevention, treatment or cure of a disease. 4D pharma has developed a proprietary platform, MicroRx®, that rationally identifies Live Biotherapeutics based on a deep understanding of function and mechanism.

4D pharma's Live Biotherapeutic products (LBPs) are orally delivered single strains of bacteria that are naturally found in the healthy human gut. The Company has five clinical programs, namely a Phase I/II study of MRx0518 in combination with KEYTRUDA® (pembrolizumab) in solid tumors, a Phase I study of MRx0518 in a neoadjuvant setting for patients with solid tumors, a Phase I study of MRx0518 in patients with pancreatic cancer, a Phase I/II study of MRx-4DP0004 in asthma, and Blautix® in irritable bowel syndrome (IBS) which has completed a successful Phase II trial. Preclinical-stage programs include candidates for CNS disease such as Parkinson's disease and other neurodegenerative conditions. The Company has a research collaboration with MSD, a tradename of Merck & Co., Inc., Kenilworth, NJ, USA, to discover and develop Live Biotherapeutics for vaccines.

For more information, refer to https://www.4dpharmaplc.com.

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**Forward-Looking Statements**

This announcement contains “forward-looking statements.” All statements other than statements of historical fact contained in this announcement, including without limitation statements regarding the efficacy of Live Biotherapeutics including MRx-4DP0004, its ability to impact the treatment of asthma, unmet medical need in asthma, and effectiveness of the MicroRx platform are forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the United States Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are often identified by the words “believe,” “expect,” “anticipate,” “plan,” “intend,” “foresee,” “should,” “would,” “could,” “may,” “estimate,” “outlook” and similar expressions, including the negative thereof. The absence of these words, however, does not mean that the statements are not forward-looking. These forward-looking statements are based on the Company’s current expectations, beliefs and assumptions concerning future developments and business conditions and their potential effect on the Company. While management believes that these forward-looking statements are reasonable as and when made, there can be no assurance that future developments affecting the Company will be those that it anticipates.

All of the Company’s forward-looking statements involve known and unknown risks and uncertainties, some of which are significant or beyond its control, and assumptions that could cause actual results to differ materially from the Company’s historical experience and its present expectations or projections. The foregoing factors and the other risks and uncertainties that affect the Company’s business, including the risks relating to the efficacy of its Live Biotherapeutic drug candidates including MRx-4DP0004, risk related to safety of investigational therapeutics, clinical development risk, and those additional risks and uncertainties described the documents filed by the Company with the US Securities and Exchange Commission (“SEC”), should be carefully considered. The Company wishes to caution you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. The Company undertakes no obligation to publicly update or revise any of its forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise, except to the extent required by law.