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 2023

Commission File Number: 001-40106

4D pharma plc

(Translation of Registrant's name into English)

5th Floor, 9 Bond Court Leeds LS1 2JZ United Kingdom Tel: +44 (0) 113 895 013

(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):

On February 2, 2023, 4D pharma plc (the "Company," "4D," "4D pharma," "we," "us" or "our") issued a press release entitled "4D pharma Announces Updated Results from the Renal Cell Carcinoma Cohort of the Phase I/II Study of the Combination of MRx0518 and KEYTRUDA® (pembrolizumab)" regarding updated clinical data from Part B of its signal finding study of MRx0518 in combination with Merck & Co, Inc.'s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with solid tumors that have progressed on a prior immune checkpoint inhibitor.

A copy of the press release is attached as Exhibit 99.1 to this current report on Form 6-K and is incorporated by reference herein. This press release is incorporated by reference into the registration statements on Form F-3 (File No. 333-263372 and File No. 333-264419) of 4D pharma plc, filed with the U.S. Securities and Exchange Commission, to be a part thereof from the date on which this press release is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

99.1 Press Release, dated February 2, 2023.

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 7, 2023

/s/ James Clark James Clark

Administrator

4D pharma plc

4D pharma plc (in administration)

4D pharma Announces Updated Results from the Renal Cell Carcinoma Cohort of the Phase I/II Study of the Combination of MRx0518 and KEYTRUDA[®] (pembrolizumab)

- Further to prior announcement of having met the primary efficacy endpoint, an additional patient is confirmed as having a response

- Strengthens strategic focus on developing MRx0518 in IO combinations in RCC

Leeds, UK, February 2, 2023 – 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 updated clinical data from Part B of its signal finding study of MRx0518 in combination with MSD's anti-PD-1 therapy, KEYTRUDA[®] (pembrolizumab) in patients with solid tumors that have progressed on a prior immune checkpoint inhibitor (ICI).

The primary efficacy endpoint for Part B of the study is more than three out of 30 patients per tumor group achieving clinical benefit, defined as complete response, partial response, or stable disease for at least six months. In March 2022, it was announced that 4 patients in the RCC cohort had experienced durable stable disease.

At the time 4D pharma plc was placed into administration it was agreed that patient recruitment into the study would be placed on temporary pause but patients who had already started treatment would be allowed to continue. There were 2 Part B RCC patients on treatment at the time of administration.

Today, 4D pharma is pleased to announce that one of these patients is experiencing a partial response. Part B of the study has to date enrolled 22 patients with RCC, of which 5 out of 20 evaluable patients have achieved clinical benefit. To date, Part B of the study has enrolled 51 patients of up to a total of 120 patients with RCC, non-small cell lung cancer, bladder cancer, and head and neck squamous cell carcinoma. MRx0518 continues to be safe and well tolerated and 5 patients are continuing on treatment.

The study is being conducted in heavily pre-treated metastatic patients with solid tumors who have previously experienced clinical benefit on prior ICI therapy and subsequently developed progressive disease. The study is being conducted in collaboration with MSD (Merck & Co., Inc., Kenilworth, NJ, USA).

"Despite recent setbacks in the microbiome field experienced by other companies and the limitations on patient recruitment as a result of the administration, we are delighted that patients continue to benefit from the trial treatment. We continue to build on the body of evidence for the future development of MRx0518 and 4D's approach to Live Biotherapeutics" commented Dr. Alex Stevenson, Chief Scientific Officer, 4D pharma. "Together with the clinical, safety and biomarker data we have generated in the wider MRx018 programme, it is clear that there is an opportunity to take MRx0518 into earlier lines of treatment to improve outcomes with immunotherapy. While the safety and tolerability of MRx0518 lends itself to multiple combinations and indications, the data we have generated in RCC suggests that this provides our most viable route to market."



4D pharma is in discussion regarding next steps for this study and future pivotal studies with partners and Key Opinion Leaders.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

On 24 June 2022, David Pike and James Clark of Interpath Advisory were appointed as administrators of 4D Pharma plc. The administrators make no statement or representation in respect of the announcement.

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 MRx0051 and MRx0004 in asthma, and Blautix® in irritable bowel syndrome (IBS) which has completed a successful Phase II trial. A Phase I study of MRx0005 and MRx0029 in patients with Parkinson's disease is expected to commence in 2022. Additional preclinical-stage programs include candidates for CNS disease, immune-inflammatory conditions and cancer. The Company has a research collaboration with MSD (Merck & Co., Inc., Kenilworth, NJ, USA), to discover and develop Live Biotherapeutics for vaccines.

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

Contact Information:

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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 its Live Biotherapeutics including MRx0006, use of the MicroRx® platform to identify candidates, and the safety and efficacy of Live Biotherapeutics for the treatment of conditions of the central nervous system (CNS), 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," "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 present expectations or projections. The foregoing factors and the other risks that could cause actual results to differ materially include risks relating to the efficacy of its Live Biotherapeutic drug candidates including MRx0006, risk related to safety of investigational therapeutics, pre-clinical and clinical development risk, and those additional risks and uncertainties described in the documents filed by the Company with the US Securities and Exchange Commission ("SEC"). 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.