
**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 **May 2021**

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 Completion of Phase II Trials

On May 24, 2021, 4D pharma plc (the “Company”) issued a press release to announce additional positive data from its completed Phase II trial of LBP Blautix® in subjects with irritable bowel syndrome with constipation (IBS-C) or with diarrhea (IBS-D). A copy of the poster can be found on the Company’s website on www.4dpharmapl.com.

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.

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: May 25, 2021

/s/ Duncan Peyton

Duncan Peyton
Chief Executive Officer

INDEX TO EXHIBITS

**Exhibit
Number** **Exhibit Title**

99.1 [Press Release, dated May 24, 2021.](#)



4D pharma Presents Additional Positive Results of Phase II Study of Blautix® for the Treatment of Irritable Bowel Syndrome

New data demonstrating clinical activity in both IBS-C and IBS-D was presented at Digestive Disease Week 2021

Company to host webcast on Tuesday, May 25, 2021 at 12:00 p.m. EDT

Leeds, UK, May 24, 2021 – 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 positive data from its completed Phase II trial of LBP Blautix® in subjects with irritable bowel syndrome with constipation (IBS-C) or with diarrhea (IBS-D).

The data has been presented in a poster session at Digestive Disease Week (DDW), on May 22, 2021, by Professor Eamonn Quigley, M.D., Head of Gastroenterology and Hepatology at Houston Methodist Hospital, Professor of Medicine at Weill Cornell Medical, and Chief Investigator of the study.

4D pharma previously announced topline efficacy and safety results from the trial, conducted in the US, UK and Ireland, in October 2020. Further analysis of the data has revealed strong and statistically significant activity on the key symptom of bowel habit, a potential approvable primary endpoint per regulatory guidelines. In addition, analysis of the data by geographical region shows that earlier topline results were impacted by an unusually high placebo response in patients in the UK and Ireland, and enhanced positive signals were seen in the larger US population.

Single strain LBP Blautix is the first therapeutic globally to have demonstrated efficacy in both IBS-C and IBS-D. The clinically meaningful overall response rates and improvements in bowel habit in both IBS-C and IBS-D in this signal finding Phase II trial, in spite of an unexpectedly high placebo response in certain patient groups, are highly encouraging for subsequent larger studies with increased statistical power.

“Following the announcement of the topline results in October, 4D pharma has been able to review the data in more detail. We have also discussed the results with internationally renowned key opinion leaders and patient groups. We are encouraged by the positive outcomes of this additional analysis, and we strongly believe that this signal finding study supports the continued development of Blautix as a novel treatment for IBS,” said Dr. Alex Stevenson, Chief Scientific Officer, 4D pharma. *“The Phase II results, in conjunction with regulatory guidance and KOL discussions, provide a clear and viable path forward for 4D pharma to continue to develop Blautix to address a significant unmet need. Topline results were significantly impacted by an unusually high placebo response in certain geographical patient groups. Despite this, the activity of Blautix relative to placebo in this Phase II study is competitive with approved IBS therapeutics. We are pleased to now share our additional positive findings following more detailed analysis of the clinical data. With the vital learnings we have gained, we are now even more enthusiastic about the chances of success in subsequent, larger, well-powered studies.”*

“The idea of a single, safe, effective therapeutic able to address multiple sub-types of IBS is a hugely exciting proposition for both patients and clinicians. The level of efficacy achieved by Blautix in IBS-C and IBS-D is very encouraging for larger pivotal studies,” said Professor Eamonn Quigley, Chief Investigator of the study. *“Importantly, the Phase II study used robust enrolment criteria and endpoints, setting the program up well for any pivotal studies. The efficacy and clean safety profile of Blautix presents an attractive package and a competitive position compared to what is currently available to prescribe to IBS patients.”*

The signal finding Phase II study was a multi-centre, randomised, double-blind, placebo-controlled study. It enrolled 353 patients in the US, UK and Ireland with IBS-C or IBS-D as defined by the Rome IV criteria, and moderate or severe IBS symptom severity score (IBS-SSS) of ≥ 175 at screening (158 IBS-C and 195 IBS-D patients). Each sub-type cohort was randomized 1:1 to receive oral Blautix or placebo, two capsules twice daily, for 8 weeks. The study was designed to generate signals of activity in both IBS-C and IBS-D and to define key parameters for a pivotal program.

The previously announced overall responder rate (ORR) primary endpoint was assessed in all randomized subjects (N=353). ORR was also assessed in all patients evaluable for efficacy at eight weeks (N=316). Bowel habit and abdominal pain, the two components of the overall responder endpoint, were also analyzed independently. Post-hoc analyses of efficacy readouts by geographic region and gender subsets were also conducted.

Additional Efficacy Data

In the post-hoc sub-group analysis, in evaluable patients (IBS-C, N=147; IBS-D N=169), Blautix demonstrated the following:

- Statistically significant improvements in bowel habit in IBS-D (Blautix 62.0% vs placebo 47.4%, $p=0.042$), and a strong effect nearing significance in IBS-C (Blautix 53.8% vs placebo 39.3%, $p=0.054$) in patients across all geographic regions.
- Consistent improvements in bowel habit in patients receiving Blautix between geographic regions.
- An enhanced effect size in US patients due to a lower placebo response, achieving a statistically significant improvement in bowel habit in both IBS-C (Blautix 62.3% vs placebo 42.6%, $p=0.028$) and IBS-D (Blautix® 53.7% vs 28.6%, $p=0.014$).
- Patients receiving Blautix reported progressive decreases in abdominal pain intensity over the treatment period. After eight weeks of treatment, evaluable IBS-C and IBS-D patients receiving Blautix reported an average decrease from baseline in weekly abdominal pain scores of 29.7% and 34.4%, respectively.
- Analysis of ORR by geographic region demonstrated comparable response rates in patients receiving Blautix regardless of region. This analysis did, however, identify a markedly greater placebo response in patients enrolled in the UK and Ireland compared to those enrolled in the US.
- In evaluable US patients, Blautix demonstrated a more than two-fold greater ORR than placebo in IBS-D (Blautix 29.3% vs placebo 14.3%, $p=0.07$), and a clinically meaningful 73% improvement in ORR over placebo in IBS-C (Blautix 28.3% vs placebo 16.4%, $p=0.096$).
- Placebo response rates were notably higher in UK and Ireland patients with IBS-C (Blautix 22.2% vs placebo 20.0%, $p=0.5$) and IBS-D (Blautix 25.6% vs placebo 27.5%, $p=0.5$).
- A particularly strong, statistically significant overall response rate was observed in female IBS-D subjects across all regions (Blautix 34.6% vs placebo 19.0%, $p=0.05$). This effect was enhanced and highly significant in US female IBS-D subjects (Blautix 37.9% vs placebo 9.4%, $p=0.01$).

Subjects in all regions met the same enrolment criteria, and there were no notable differences in baseline characteristics between regions. The Company has discussed the high placebo response in UK and Ireland patients with international key opinion leaders (KOLs) and IBS patient advocate groups, and identified a number of potential factors relating to placebo response and unrelated to study drug effectiveness in different populations.



Safety Data

As previously reported, Blautix demonstrated a safety profile comparable to placebo, with no treatment-related severe adverse events or serious adverse events. The most common adverse events were mild or moderate in severity, and were limited to (IBS-C and IBS-D cohorts combined) upper respiratory tract infection (3.9% vs placebo 3.7%), nasopharyngitis (3.9% vs placebo 1.1%), diarrhea (3.4% vs placebo 1.1%) and abdominal pain (2.3% vs placebo 2.1%).

The Company continues to evaluate the Blautix Phase II data and plans to engage in regulatory discussions in the second half of 2021.

A copy of the poster is available via the Posters & Publications area of the 4D pharma website at www.4dpharmapl.com.

Conference Call and Webcast Details

4D pharma will host a virtual event to review the additional data presented at DDW 2021, and how this relates to the current IBS treatment landscape. The event will take place on Tuesday, May 25, 2021 at 5:00pm BST (12:00pm EDT). The event will feature a presentation from 4D pharma management followed by an analyst Q&A session.

A live webcast of the event will be available via the Events section of the 4D pharma website at www.4dpharmapl.com. To access the call, please dial +1-760-294-1674 (United States) or +44-203-059-58-69 (United Kingdom) and reference Conference ID 20210360. A replay of the webcast will be available following the event.

About Blautix®

Blautix® is a single strain Live Biotherapeutic product (LBP), being developed as a treatment for both IBS-C and IBS-D. Pre-clinical studies demonstrated its ability to address visceral hypersensitivity and other symptoms of IBS and increase microbiome diversity. A Phase I study in healthy volunteers and IBS patients showed that Blautix was well tolerated and an improvement in symptoms was also reported relative to placebo. A Phase II trial demonstrated an impact on overall response with regards to bowel habit and abdominal pain in both IBS-C and IBS-D. Blautix was well tolerated, with a safety profile comparable to placebo. Further information on the Phase II study can be found at ClinicalTrials.gov Identifier: NCT03721107.

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 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 six clinical programmes, namely a Phase I/II study of MRx0518 in combination with KEYTRUDA (pembrolizumab) in solid tumours, a Phase I study of MRx0518 in a neoadjuvant setting for patients with solid tumours, a Phase I study of MRx0518 in patients with pancreatic cancer, a Phase I/II study of MRx-4DP0004 in asthma, a Phase II study of MRx-4DP0004 in patients hospitalised with COVID-19, and Blautix® in Irritable Bowel Syndrome (IBS) which has completed a successful Phase II trial. Preclinical-stage programmes 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.4dpharmapl.com>



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 4D’s pharma’s development plans for Blautix, 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 could cause actual results to differ materially include the safety and efficacy of its Live Biotherapeutic Product drug candidates including Blautix®, timelines for regulatory engagement, the need for additional safety and efficacy data to support regulatory approval, 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.

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