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 September 2024

Commission File Number 001-39670

PURETECH HEALTH PLC
(Translation of registrant's name into English)

6 Tide Street, Suite 400
Boston, Massachusetts 02210
(Address of principal executive office)

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): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

Press Release

On September 27, 2024, PureTech Health plc (LSE: PRTC, Nasdaq: PRTC) (the "Company") issued a press release announcing that PureTech-invented KarXT received U.S. Food and Drug Administration approval for the treatment of schizophrenia in adults.

The press release is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

Exhibits

99.1 Press Release of PureTech Health plc, dated September 27, 2024, titled "PureTech-Invented KarXT Receives U.S. Food and Drug Administration Approval for the Treatment of Schizophrenia in Adults".

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.

PURETECH HEALTH PLC

Date: September 27, 2024

By: /s/ Bharatt Chowrira
Name: Bharatt Chowrira
Title: Chief Executive Officer

Exhibit 99.1

27 September 2024

PureTech Health plc

PureTech-Invented KarXT Receives U.S. Food and Drug Administration Approval for the Treatment of Schizophrenia in Adults

Milestone triggers payments to PureTech totaling $29 million under agreements with Royalty Pharma and PureTech's Founded Entity, Karuna Therapeutics, which was acquired by Bristol Myers Squibb in March 2024, and unlocks potential future payments related to additional milestones and royalties

Bristol Myers Squibb to market KarXT as Cobenfy™[1]

Cobenfy is the first new drug mechanism approved in over 50 years for the treatment of schizophrenia in adults

PureTech Health plc (Nasdaq: PRTC, LSE: PRTC) ("PureTech" or the "Company"), a clinical-stage biotherapeutics company dedicated to changing the lives of patients with devastating diseases, today announced that KarXT (xanomeline and trospium chloride), which was initially invented and advanced by PureTech, has received U.S. Food and Drug Administration ("FDA") approval for the treatment of schizophrenia in adults. The FDA approval triggers two separate milestone payments to PureTech totaling $29 million under agreements with Royalty Pharma and PureTech's Founded Entity, Karuna Therapeutics, which was acquired by Bristol Myers Squibb (NYSE: BMY) ("BMS") in March of 2024. Under these agreements, PureTech is also entitled to potential future payments related to additional milestones as well as approximately 2% royalties on net annual sales over $2 billion. Following the acquisition of Karuna, KarXT is now under the stewardship of BMS and will be marketed as Cobenfy.

Cobenfy was invented at PureTech by combining two biologically active molecules – xanomeline and trospium chloride – to address a tolerability challenge that had held back a potential new class of medicines for the treatment of neuropsychiatric conditions, such as schizophrenia. Consistent with its unique model of drug development, PureTech advanced Cobenfy by founding Karuna Therapeutics, which later became a publicly traded company on Nasdaq.

Eric Elenko, PhD, Co-founder and President of PureTech said: "The FDA approval of Cobenfy is a significant milestone in our mission to transform the lives of patients with devastating diseases. Our initial hypothesis was that we could overcome the tolerability issues that had hindered the development of an otherwise promising drug, xanomeline, and we were able to test and validate this concept early on. We are immensely proud that our dedication to this program has led to the first major innovation in decades for those living with schizophrenia, and I am equally pleased that our unique approach to R&D has delivered yet another novel therapeutic to patients. Congratulations to the teams at Karuna and BMS on this historic accomplishment."

The FDA approval of Cobenfy is further validation of PureTech's model and a hallmark of how it creates value both clinically and financially. PureTech's monetization of equity holdings in Karuna, including gross proceeds from the BMS acquisition of Karuna, and a strategic royalty agreement with Royalty Pharma have enabled PureTech to generate approximately $1.1 billion to date after directing $18.5 million toward Karuna's founding and Cobenfy's development. PureTech's business model is designed to repeat and scale this type of outcome, and proceeds from the success of Cobenfy have enabled PureTech to self-fund the advancement of several programs – including LYT-100 (deupirfenidone), LYT-200 (anti-galectin-9 mAb), and the Glyph™ platform supporting the pipeline of Seaport Therapeutics.

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[1] Cobenfy is a trademark of Bristol Myers Squibb.

Bharatt Chowrira, PhD, JD, Chief Executive Officer of PureTech said: “Congratulations to the Karuna and BMS teams for delivering a groundbreaking treatment to people with schizophrenia. The FDA approval of Cobenfy is a testament to our unique R&D engine, which has now produced three FDA approved therapeutics. We’ve applied this approach across our portfolio, from our late-stage Internal Program LYT-100 (deupirfenidone) to our newly launched Founded Entity, Seaport Therapeutics, and we will continue to leverage this successful drug development model as we enter our next phase of innovation.”

PureTech’s next wave of innovation continues to focus on validated biologic and small molecule modalities with human clinical data in diseases with significant unmet need. LYT-100 (deupirfenidone) is PureTech’s wholly-owned program in development for the treatment of idiopathic pulmonary fibrosis (IPF), a rare progressive lung disease with no cure. The LYT-100 program leverages extensive prior clinical data and follows the same blueprint used with Cobenfy to unlock the full therapeutic potential of an efficacious but poorly tolerated medicine. PureTech anticipates topline data from the Phase 2b clinical trial of LYT-100 in patients with IPF by the end of the year, as well as additional readouts from its oncology program, LYT-200 (anti-galectin-9 monoclonal antibody).

Important Safety Information

CONTRAINDICATIONS

COBENFY is contraindicated in patients with:

- urinary retention
- moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment
- gastric retention
- history of hypersensitivity to COBENFY or trospium chloride. Angioedema has been reported with COBENFY and trospium chloride.
- untreated narrow-angle glaucoma

WARNINGS AND PRECAUTIONS

Risk of Urinary Retention: COBENFY can cause urinary retention. Geriatric patients and patients with clinically significant bladder outlet obstruction and incomplete bladder emptying (e.g., patients with benign prostatic hyperplasia (BPH), diabetic cystopathy) may be at increased risk of urinary retention. COBENFY is contraindicated in patients with pre-existing urinary retention and is not recommended in patients with moderate or severe renal impairment.

In patients taking COBENFY, monitor for symptoms of urinary retention, including urinary hesitancy, weak stream, incomplete bladder emptying, and dysuria. Instruct patients to be aware of the risk and promptly report symptoms of urinary retention to their healthcare provider. Urinary retention is a known risk factor for urinary tract infections. In patients with symptoms of urinary retention, consider reducing the dose of COBENFY, discontinuing COBENFY, or referring patients for urologic evaluation as clinically indicated.

Risk of Use in Patients with Hepatic Impairment: Patients with hepatic impairment have higher systemic exposures of xanomeline, a component of COBENFY, compared to patients with normal hepatic function, which may result in increased incidence of COBENFY-related adverse reactions.

COBENFY is contraindicated in patients with moderate or severe hepatic impairment. COBENFY is not recommended in patients with mild hepatic impairment.

Assess liver enzymes prior to initiating COBENFY and as clinically indicated during treatment.

Risk of Use in Patients with Biliary Disease: In clinical studies with COBENFY, transient increases in liver enzymes with rapid decline occurred, consistent with transient biliary obstruction due to biliary contraction and possible gallstone passage.

COBENFY is not recommended for patients with active biliary disease such as symptomatic gallstones. Assess liver enzymes and bilirubin prior to initiating COBENFY and as clinically indicated during treatment. The occurrence of symptoms such as dyspepsia, nausea, vomiting, or upper abdominal pain should prompt assessment for gallbladder disorders, biliary disorders, and pancreatitis, as clinically indicated.

Discontinue COBENFY in the presence of signs or symptoms of substantial liver injury such as jaundice, pruritus, or alanine aminotransferase levels more than five times the upper limit of normal or five times baseline values.

Decreased Gastrointestinal Motility: COBENFY contains trospium chloride. Trospium chloride, like other antimuscarinic agents, may decrease gastrointestinal motility. Administer COBENFY with caution in patients with gastrointestinal obstructive disorders because of the risk of gastric retention. Use COBENFY with caution in patients with conditions such as ulcerative colitis, intestinal atony, and myasthenia gravis.

Risk of Angioedema: Angioedema of the face, lips, tongue, and/or larynx has been reported with COBENFY and trospium chloride, a component of COBENFY. In one case, angioedema occurred after the first dose of trospium chloride. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, discontinue COBENFY and initiate appropriate therapy and/or measures necessary to ensure a patent airway. COBENFY is contraindicated in patients with a history of hypersensitivity to trospium chloride.

Risk of Use in Patients with Narrow-angle Glaucoma: Pupillary dilation may occur due to the anticholinergic effects of COBENFY. This may trigger an acute angle closure attack in patients with anatomically narrow angles. In patients known to have anatomically narrow angles, COBENFY should only be used if the potential benefits outweigh the risks and with careful monitoring.

Increases in Heart Rate: COBENFY can increase heart rate. Assess heart rate at baseline and as clinically indicated during treatment with COBENFY.

Anticholinergic Adverse Reactions in Patients with Renal Impairment: Trospium chloride, a component of COBENFY, is substantially excreted by the kidney. COBENFY is not recommended in patients with moderate or severe renal impairment (estimated glomerular filtration rate (eGFR) <60 mL/min). Systemic exposure of trospium chloride is higher in patients with moderate and severe renal impairment. Therefore, anticholinergic adverse reactions (including dry mouth, constipation, dyspepsia, urinary tract infection, and urinary retention) are expected to be greater in patients with moderate and severe renal impairment.

Central Nervous System Effects: Trospium chloride, a component of COBENFY, is associated with anticholinergic central nervous system (CNS) effects. A variety of CNS anticholinergic effects have been reported with trospium chloride, including dizziness, confusion, hallucinations, and somnolence.

Monitor patients for signs of anticholinergic CNS effects, particularly after beginning treatment or increasing the dose. Advise patients not to drive or operate heavy machinery until they know how COBENFY affects them. If a patient experiences anticholinergic CNS effects, consider dose reduction or drug discontinuation.

Most Common Adverse Reactions (≥5% and at least twice placebo): nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastroesophageal reflux disease.

Use in Specific Populations:

- Moderate or Severe Renal Impairment: Not recommended
- Mild Hepatic Impairment: Not recommended

COBENFY (xanomeline and trospium chloride) is available in 50mg/20mg, 100mg/20mg, and 125mg/30mg capsules.

Please see U.S. Full Prescribing Information , including Patient Information .

About PureTech Health

PureTech is a clinical-stage biotherapeutics company dedicated to giving life to new classes of medicine to change the lives of patients with devastating diseases. The Company has created a broad and deep pipeline through its experienced research and development team and its extensive network of scientists, clinicians and industry leaders that is being advanced both internally and through its Founded Entities. PureTech's R&D engine has resulted in the development of 29 therapeutics and therapeutic candidates, including three that have been approved by the U.S. Food and Drug Administration. A number of these programs are being advanced by PureTech or its Founded Entities in various indications and stages of clinical development, including registration enabling studies. All of the underlying programs and platforms that resulted in this pipeline of therapeutic candidates were initially identified or discovered and then advanced by the PureTech team through key validation points.

For more information, visit www.puretechhealth.com or connect with us on X (formerly Twitter) @puretechh.

Cautionary Note Regarding Forward-Looking Statements

This press release contains statements that are or may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation those related to additional milestones or royalties potentially due to PureTech in relation to KarXT/Cobenfy, PureTech's development plans and the timing of data readouts, including as related to LYT-100 and LYT-200, and our future prospects, developments and strategies. The forward-looking statements are based on current expectations and are subject to known and unknown risks, uncertainties and other important factors that could cause actual results, performance and achievements to differ materially from current expectations, including, but not limited to, those risks, uncertainties and other important factors described under the caption "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2023, filed with the SEC and in our other regulatory filings. These forward-looking statements are based on assumptions regarding the present and future business strategies of the Company and the environment in which it will operate in the future. Each forward-looking statement speaks only as at the date of this press release. Except as required by law and regulatory requirements, we disclaim any obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.

Contact:

PureTech
Public Relations
publicrelations@puretechhealth.com
Investor Relations

UK/EU Media
Ben Atwell, Rob Winder
+44 (0) 20 3727 1000
puretech@fticonsulting.com

US Media
Nichole Bobbyn
+1 774 278 8273
nichole@tenbridgecommunications.com