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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 29, 2024

Immunocore Holdings plc

(Exact name of registrant as specified in its Charter)

England and Wales	**001-39992**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
92 Park Drive, Milton Park **Abingdon, Oxfordshire,** **United Kingdom** **(Address of principal executive offices)**		**OX14 4RY** **(Zip Code)**

+44 1235 438600
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares, each representing one ordinary share, nominal value £0.002 per share	**IMCR**	**The Nasdaq Stock Market LLC**
Ordinary share, nominal value £0.002 per share*	*	**The Nasdaq Stock Market LLC**

* *Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.*

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On May 29, 2024, Immunocore Holdings plc (the "Company") issued a press release announcing that its TEBE-AM Phase 2/3 clinical trial has been converted into a Phase 3 registrational clinical trial evaluating KIMMTRAK for previously treated advanced cutaneous melanoma, following recent consultation with the U.S. Food and Drug Administration. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report") and is incorporated by reference herein.

Cautionary Note Regarding Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Current Report are forward-looking statements, including without limitation, statements regarding the clinical development of KIMMTRAK for previously treated advanced cutaneous melanoma, the conversion of the Company's Phase 2/3 TEBE-AM clinical trial into a single registrational Phase 3 trial, current and future clinical trial progress and expected timing of regulatory approvals. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

Any forward-looking statements are based on management's current expectations and beliefs of future events and are subject to a number of risks and uncertainties that could cause actual events or results to differ materially and adversely from those set forth in or implied by such forward-looking statements, many of which are beyond the Company's control. These risks and uncertainties include, but are not limited to, the Company's ability to conduct ongoing and planned clinical trials; the Company's ability to obtain and maintain regulatory approval of its product candidates, including expanded indications of KIMMTRAK; the delay of any current or planned clinical trials, whether due to patient enrollment delays or otherwise; the Company's ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; competition with respect to market opportunities; unexpected safety or efficacy data observed during preclinical studies or clinical trials; and actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or future regulatory approval. These and other risks and uncertainties are described in greater detail in the section titled "Risk Factors" in the Company's filings with the Securities and Exchange Commission, including the Company's most recent Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on February 28, 2024, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the Securities and Exchange Commission. While the Company may elect to update such forward-looking statements at some point in the future, the Company disclaims any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report.

Item 9.01. Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated May 29, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

IMMUNOCORE HOLDINGS PLC

Dated: May 30, 2024

By: /s/ Bahija Jallal, Ph.D.
Name: Bahija Jallal, Ph.D.
Title: Chief Executive Officer

IMMUNOCORE

Immunocore converts Phase 2/3 TEBE-AM clinical trial into registrational Phase 3 trial evaluating KIMMTRAK for previously treated advanced cutaneous melanoma

Following recent consultation with FDA, all patients randomized from start of TEBE-AM Phase 2/3 trial will be included in the Phase 3 intent-to-treat population

Phase 3 will continue three arms: KIMMTRAK monotherapy, KIMMTRAK in combination with pembrolizumab, and control

Expected to accelerate time to final Phase 3 overall survival analysis

(OXFORDSHIRE, England & CONSHOHOCKEN, PA & ROCKVILLE, MD, US, 29 May 2024) Immunocore Holdings plc (Nasdaq: IMCR) ("Immunocore" or the "Company"), a commercial-stage biotechnology company pioneering and delivering transformative immunomodulating medicines to radically improve outcomes for patients with cancer, infectious diseases and autoimmune diseases, today announced that the TEBE-AM Phase 2/3 clinical trial has been converted into a Phase 3 trial.

The Phase 2/3 TEBE-AM trial was designed to evaluate KIMMTRAK® (tebentafusp-tebn), as monotherapy and in combination with pembrolizumab, versus a control arm, for the treatment of patients with previously treated advanced cutaneous melanoma. The trial was originally designed as an adaptive Phase 2/3 trial with the optionality to review Phase 2 data and drop an arm. Following consultation with the FDA, the Company has decided to conduct the trial solely as a Phase 3 with the primary endpoint of overall survival. As a result of the recent rapid accrual, the Company projects that the Phase 3 trial would be mostly enrolled by the time the Phase 2 overall survival would have matured. In addition, the three arm Phase 3 will allow more robust testing of KIMMTRAK as monotherapy and in combination versus a control arm. Finally, with all patients randomized to date to be included in the intent-to-treat population, the time to final analysis of the Phase 3 trial will be accelerated.

Mark Moyer, SVP, Regulatory Affairs, Immunocore said: "The decision to launch a registrational trial in cutaneous melanoma was based on KIMMTRAK's overall survival benefit in uveal melanoma, and promising clinical activity as monotherapy and in combination with immune checkpoint therapy in Phase 1 cutaneous melanoma trials. To allow robust testing of two KIMMTRAK regimens and to accelerate the time to primary analysis, we decided, in consultation with the FDA, to amend the protocol into a single Phase 3 registrational study."

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The registrational TEBE-AM trial was initiated following results from a Phase 1b trial of tebentafusp in combination with checkpoint inhibitors in metastatic cutaneous melanoma (mCM). The Phase 1b data showed that the maximum target doses of tebentafusp (68 mcg) plus durvalumab (20 mg/kg) were well tolerated, and that, in mCM patients who progressed on prior anti-PD(L)1, the combination demonstrated a one-year overall survival rate of ~75%.

About ImmTAC® molecules for cancer

Immunocore's proprietary T cell receptor (TCR) technology generates a novel class of bispecific biologics called ImmTAC (Immune mobilizing monoclonal TCRs Against Cancer) molecules that are designed to redirect the immune system to recognize and kill cancerous cells. ImmTAC molecules are soluble TCRs engineered to recognize intracellular cancer antigens with ultra-high affinity and selectively kill these cancer cells via an anti-CD3 immune-activating effector function. Based on the demonstrated mechanism of T cell infiltration into human tumors, the ImmTAC mechanism of action holds the potential to treat hematologic and solid tumors, regardless of mutational burden or immune infiltration, including immune "cold" low mutation rate tumors.

About TEBE-AM - Phase 3 registrational trial with tebentafusp in previously treated advanced cutaneous melanoma

The Phase 3 TEBE-AM trial is randomizing patients with second-line or later cutaneous melanoma who have progressed on an anti-PD1, received prior ipilimumab and, if applicable, received a BRAF kinase inhibitor. Patients are randomized to one of three arms, including tebentafusp, as monotherapy or in combination with an anti-PD1, and a control arm. The primary endpoint is overall survival.

About Cutaneous Melanoma

Cutaneous melanoma (CM) is the most common form of melanoma. It is the most aggressive skin carcinoma and is associated with the vast majority of skin cancer-related mortality. The majority of patients with CM are diagnosed before metastasis and survival remains poor for the large proportion of patients with metastatic disease. Despite recent progress in advanced melanoma therapy, there is still an unmet need for new therapies that improve first-line response rates and duration of response as well as for patients who are refractory to first-line treatments.

About Uveal Melanoma

Uveal melanoma is a rare and aggressive form of melanoma, which affects the eye. Although it is the most common primary intraocular malignancy in adults, the diagnosis is rare, and up to 50% of people with uveal melanoma will eventually develop metastatic disease. Unresectable or metastatic uveal melanoma typically has a poor prognosis and had no approved treatment until KIMMTRAK.

About KIMMTRAK®

KIMMTRAK is a novel bispecific protein comprised of a soluble T cell receptor fused to an anti-CD3 immune-effector function. KIMMTRAK specifically targets gp100, a lineage antigen expressed in melanocytes and melanoma. This is the first molecule developed using Immunocore's ImmTAC technology platform designed to redirect and activate T cells to recognize and kill tumor cells. KIMMTRAK has been approved for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma in the United States, European Union, Canada, Australia, and the United Kingdom.

IMPORTANT SAFETY INFORMATION

Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

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Skin Reactions

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

Embryo-Fetal Toxicity

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.
The most common adverse reactions (≥30%) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common (≥50%) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.
For more information, please see full Summary of Product Characteristics (SmPC) or full U.S. Prescribing Information (including BOXED WARNING for CRS).

About KIMMTRAKConnect

Immunocore is committed to helping patients who need KIMMTRAK obtain access via our KIMMTRAKConnect program. The program provides services with dedicated nurse case managers who provide personalized support, including educational resources, financial assistance, and site of care coordination. To learn more, visit KIMMTRAKConnect.com or call 844-775-2273.

About Immunocore

Immunocore is a commercial-stage biotechnology company pioneering the development of a novel class of TCR bispecific immunotherapies called ImmTAX – Immune mobilizing monoclonal TCRs Against X disease – designed to treat a broad range of diseases, including cancer, autoimmune, and infectious disease. Leveraging its proprietary, flexible, off-the-shelf ImmTAX platform, Immunocore is developing a deep pipeline in multiple therapeutic areas, including nine active clinical and pre-clinical programs in oncology, infectious diseases, and autoimmune diseases. The Company's most advanced oncology TCR therapeutic, KIMMTRAK has been approved for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma in the United States, European Union, Canada, Australia, and the United Kingdom.

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Forward Looking Statements

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