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 December, 2024

Commission file number: 001-37891

AC IMMUNE SA

(Exact Name of Registrant as Specified in Its Charter)

EPFL Innovation Park
Building B
1015 Lausanne, Switzerland

(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 ☐

On December 10, 2024, AC Immune SA issued a press release reporting interim safety and tolerability data from the ABATE Phase 1b/2 trial of ACI-24.060 in individuals living with Down syndrome (DS).

Targeting toxic forms of amyloid beta (Abeta), ACI-24.060 is an active immunotherapy covering Abeta 1-15 (excluding Abeta T-cell epitopes). The interim analysis was based on data from the first two cohorts of individuals with DS receiving low-dose and mid-dose ACI-24.060. DS subjects in the interim analysis have been treated for up to one year, with no serious adverse events related to the study drug and no case of amyloid-related imaging abnormalities (ARIA) observed in this study population.

The ongoing ABATE study (NCT05462106) is a randomized, double-blind, placebo-controlled Phase 1b/2 trial assessing the safety, tolerability, immunogenicity and pharmacodynamic effects of the investigational immunotherapy. The study was specifically designed to support parallel development in individuals with prodromal Alzheimer's disease (AD) and non-demented adults with DS, a vulnerable population predisposed to developing AD.

ACI-24.060 has received Fast Track designation from the U.S. FDA for the treatment of AD. The Company previously reported positive interim safety, tolerability, and immunogenicity from the AD cohorts of the ABATE trial, which supported the treatment with ACI-24.060 in individuals with DS in ABATE.

The trial will now start to evaluate the high dose of ACI-24.060 in additional patients with DS. Recruitment of individuals with DS continues at ABATE trial sites in the U.S., U.K., and Spain.

A copy of the press release is attached as Exhibit 99.1 to this Report on Form 6-K.

This Report on Form 6-K (other than Exhibit 99.1 hereto) shall be deemed to be incorporated by reference into the registration statements on Form F-3 (File Nos. 333-227016, 333-249655 and 333-277940) and Form S-8 (File Nos. 333-213865, 333-216539 and 333-233019) of AC Immune SA and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated December 10, 2024

SIGNATURE

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.

AC IMMUNE SA

By: /s/ Andrea Pfeifer
Name: Andrea Pfeifer
Title: Chief Executive Officer

By: /s/ Christopher Roberts
Name: Christopher Roberts
Title: Chief Financial Officer

Date: December 10, 2024

AC Immune

PRESS RELEASE

AC Immune Reports Interim Safety Data from Phase 1b/2 ABATE Trial of ACI-24.060 in Down syndrome

- ACI-24.060 was generally safe and well tolerated in individuals with Down syndrome with no serious adverse events related to the study drug
- No cases of amyloid-related imaging abnormalities observed in this study population
- Based upon these findings, AC Immune plans to open the high-dose cohort in ABATE in individuals with Down syndrome

Lausanne, Switzerland, December 10, 2024 – AC Immune SA (NASDAQ: ACIU), a clinical-stage biopharmaceutical company pioneering precision therapeutics for neurodegenerative diseases, today announced interim safety and tolerability data from the ABATE Phase 1b/2 trial of ACI-24.060 in individuals living with Down syndrome (DS). Targeting toxic forms of amyloid beta (Abeta), ACI-24.060 is an active immunotherapy covering Abeta 1-15 (excluding Abeta T-cell epitopes). The interim analysis was based on data from the first two cohorts of individuals with DS receiving low-dose and mid-dose ACI-24.060. DS subjects in the interim analysis have been treated for up to one year, with no serious adverse events related to the study drug and no case of amyloid-related imaging abnormalities (ARIA) observed in this study population.

Dr. Anke Post, Chief Medical Officer of AC Immune SA, commented: “These interim safety data are encouraging and supportive of the potential of ACI-24.060 to provide people with Down syndrome a novel therapeutic option targeting brain Abeta pathology while providing initial favorable safety and tolerability.”

The ongoing ABATE study (NCT05462106) is a randomized, double-blind, placebo-controlled Phase 1b/2 trial assessing the safety, tolerability, immunogenicity and pharmacodynamic effects of the investigational immunotherapy. The study was specifically designed to support parallel development in individuals with prodromal Alzheimer’s disease (AD) and non-demented adults with DS, a vulnerable population predisposed to developing AD.

Dr. Mike Rafii, Medical Director of the Alzheimer’s Therapeutic Research Institute, Professor of Neurology at the Keck School of Medicine, and Coordinating Principal Investigator of the ABATE study commented: “Safety is particularly important in the Down syndrome population, in which treatments targeting amyloid pathology are urgently needed to prevent the onset and progression of Alzheimer’s disease. To date, the safety and tolerability profile of ACI-24.060 is encouraging.”

ACI-24.060 has received Fast Track designation from the U.S. FDA for the treatment of AD. The Company previously reported positive interim safety, tolerability, and immunogenicity from the AD cohorts of the ABATE trial, which supported the treatment with ACI-24.060 in individuals with DS in ABATE.

The trial will now start to evaluate the high dose of ACI-24.060 in additional patients with DS. Recruitment of individuals with DS continues at ABATE trial sites in the U.S., U.K., and Spain.

About the Phase 1b/2 ABATE Study (ClinicalTrials.gov Identifier: NCT05462106; www.abate-study.com)

The ABATE study is a Phase 1b/2, multicenter, adaptive, double-blind, randomized, placebo-controlled study to assess the safety, tolerability, immunogenicity, and pharmacodynamic effects of ACI-24.060 in subjects with prodromal AD and in adults with DS. All participants in the trial must have brain Abeta pathology confirmed by a positron emission tomography (PET) scan. Recent clinical studies and FDA approvals have validated Abeta as a disease modifying therapeutic target in AD and are supportive of Abeta PET imaging as a surrogate marker of efficacy. The ABATE trial aims at evaluating various doses/dosing regimens of ACI-24.060 in both AD and DS populations. Individuals with DS between the ages of 35 and 50 who would like to learn more can visit the ABATE Study website at www.abate-study.com to find the site nearest them.

About Alzheimer's Disease (AD) in Down Syndrome (DS)

Individuals with DS have a third copy of all or part of chromosome 21, which contains the gene that codes for amyloid-precursor protein (APP). Overproduction of APP is believed to cause the accumulation of Abeta plaques. Virtually all individuals with DS will develop Abeta plaques and AD[1], with DS-related AD sharing a similar pathophysiology and biomarkers with other forms of genetic AD. Given the predictable onset and progression of symptoms in DS-related AD, AC Immune believes ABATE's results will offer crucial insights into the ability of ACI-24.060 active immunotherapy to target brain Abeta at its early stages and offer this population a much needed therapeutic option.

About ACI-24.060

ACI-24.060, derived from AC Immune's SupraAntigen® platform, covers Abeta 1-15 which excludes T-cell epitopes. ACI-24.060 has been shown in preclinical studies to induce a strong polyclonal antibody response that matures and is maintained against both oligomeric and pyroglutamate-Abeta species, key pathological forms of Abeta believed to drive Abeta plaque formation and disease progression. ACI-24.060 is designed to enhance the formation of broad-spectrum protective antibodies with the same safety and tolerability previously demonstrated in the ACI-24 program in Phase 1 and 2 trials. This investigational candidate has the potential to efficiently inhibit plaque formation and increase plaque clearance, and thereby may reduce or prevent disease progression.

Reference

1. Lott, Ira T., and Elizabeth Head. "Dementia in Down syndrome: unique insights for Alzheimer disease research." *Nature Reviews Neurology* 15.3 (2019): 135-147.

About AC Immune SA

AC Immune SA is a clinical-stage biopharmaceutical company and a global leader in precision prevention for neurodegenerative diseases, including Alzheimer's disease, Parkinson's disease, and NeuroOrphan indications driven by misfolded proteins. The Company's two clinically validated technology platforms, SupraAntigen® and Morphomer®, fuel its broad and diversified pipeline of first- and best-in-class assets, which currently features sixteen therapeutic and diagnostic programs, including five in Phase 2 development and one in Phase 3. AC Immune has a strong track record of securing strategic partnerships with leading global pharmaceutical companies, resulting in substantial non-dilutive funding to advance its proprietary programs and >$4.5 billion in potential milestone payments plus royalties.

SupraAntigen® is a registered trademark of AC Immune SA in the following territories: AU, EU, CH, GB, JP, RU, SG and USA. Morphomer® is a registered trademark of AC Immune SA in CN, CH, GB, JP, KR, NO and RU.

The information on our website and any other websites referenced herein is expressly not incorporated by reference into, and does not constitute a part of, this press release.

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Forward looking statements

This press release contains statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or AC Immune's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include those described under the captions "Item 3. Key Information – Risk Factors" and "Item 5. Operating and Financial Review and Prospects" in AC Immune's Annual Report on Form 20-F and other filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and AC Immune does not undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forward-looking statements are qualified in their entirety by this cautionary statement.