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**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**

**Date of Report: July 18, 2024**

Commission File Number: **001-40377**

**Valneva SE**

(Translation of registrant's name into English)

**6 rue Alain Bombard**

**44800 Saint-Herblain, France**

(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 [  ]

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On July 17, 2024, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information contained in this Form 6-K, including Exhibit 99.1, is hereby incorporated by reference into the registrant's Registration Statement on Form F-3 (File No. 333-266839).

**Exhibit**

[99.1](#)      [Press release dated July 17, 2024](#)

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## 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.

Valneva SE  
(Registrant)

Date: July 18, 2024

/s/ Thomas Lingelbach  
Thomas Lingelbach  
Chief Executive Officer and President

### Phase 3 VALOR Lyme Disease Trial: Valneva and Pfizer Announce Primary Vaccination Series Completion

- *Participants completed primary vaccination series (3 doses) with VLA15*
- *Primary vaccination series to be followed by a booster approximately one year after completion*

**New York, NY and Saint-Herblain (France), July 17, 2024** – Pfizer Inc. (NYSE: PFE) and Valneva SE (Nasdaq: VALN; Euronext Paris: VLA) today announced that the participants of the Phase 3 trial “Vaccine Against Lyme for Outdoor Recreationists” (VALOR) have completed the primary vaccination series (three doses) of Lyme disease vaccine candidate VLA15. Participants will be monitored for the occurrence of Lyme disease cases until the end of the Lyme disease season in 2025.<sup>1</sup>

“The completion of the primary series of our VALOR trial is a critical step toward our goal of providing a safe and effective vaccine against Lyme disease,” said **Annaliesa Anderson, Ph.D., Senior Vice President and Head of Vaccine Research and Development, Pfizer**. “VLA15, the Lyme disease vaccine candidate we are co-developing with Valneva, is the one which has advanced the furthest along the clinical development timeline, with two Phase 3 trials in progress.”

**Juan Carlos Jaramillo, M.D., Chief Medical Officer, Valneva**, said, “We are pleased to see the progress of our Phase 3 VALOR trial. Lyme disease is the most prevalent vector-borne disease in the United States and Europe. It can result in debilitating complications and extensive healthcare treatments. Given the growing burden, high medical need, and lack of effectiveness with current interventions, there is an urgent need for novel approaches to help prevent Lyme disease.”

The VALOR trial, for which Pfizer is the sponsor, is a multicenter, placebo-controlled, randomized, observer-blinded trial conducted at sites in areas where Lyme disease is highly endemic across the U.S., Canada, and Europe. The aim of the trial is to evaluate the efficacy, safety, tolerability, immunogenicity, and lot consistency of VLA15, a 6-valent OspA-based Lyme disease vaccine candidate.<sup>1</sup> Trial participants aged 5 years and older were randomized 1:1 into two trial groups and receive four doses of either VLA15 or a saline placebo – one dose each at months 0, 2, 5-9 and a booster one year after the third dose, shortly before the peak of the next Lyme disease season.<sup>1</sup>

Subject to positive data, Pfizer plans to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) and a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in 2026.

VLA15 has shown a favorable safety profile across all dose and age groups in all clinical trials to date<sup>2,3</sup>. No safety concerns have been observed to date by an independent Data Safety Monitoring Board (DSMB) in any treatment group.<sup>2,3</sup> A second Phase 3 trial (C4601012), aiming to provide further evidence on the safety profile of VLA15 in the pediatric population between 5 and 17 years of age is ongoing; this trial completed enrollment in June 2023.

Pfizer and Valneva entered into a collaboration agreement in April 2020 to co-develop VLA15, with updates to the terms within this agreement made in June 2022.<sup>4,5</sup>

#### About VLA15

There are currently no approved human vaccines for Lyme disease, and VLA15 is the Lyme disease vaccine candidate which has advanced the furthest along the clinical development timeline, with two Phase 3 trials in progress. This investigational multivalent protein subunit vaccine uses an established mechanism of action for a Lyme disease vaccine that targets the outer surface protein A (OspA) of *Borrelia burgdorferi*, the bacteria that cause Lyme disease. OspA is a surface protein expressed by the bacteria when present in a tick. Blocking OspA inhibits the bacterium’s ability to leave the tick and infect humans. The vaccine candidate covers the six most prevalent OspA serotypes expressed by the *Borrelia burgdorferi sensu lato* species in North America and Europe.

#### About Lyme Disease

Lyme disease is a systemic infection caused by *Borrelia burgdorferi* bacteria transmitted to humans by the bite of infected *Ixodes* ticks.<sup>6</sup> It is considered the most common vector-borne illness in the Northern Hemisphere.<sup>7,8</sup> While the true incidence of Lyme disease is unknown, the Centers for Disease Control and Prevention (CDC) has estimated that approximately 476,000 people in the U.S. are diagnosed and treated each year and 129,000 cases are reported annually in Europe.<sup>8,9</sup> Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called erythema migrans or other nonspecific symptoms like fatigue, fever, headache, mild stiff neck, muscle and joint pains) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious chronic complications affecting the skin, joints (arthritis), the heart (carditis) or the nervous system.<sup>9,10</sup> The medical need for vaccination against Lyme disease is steadily increasing as the geographic footprint of the disease widens.<sup>11</sup>

#### About Pfizer: Breakthroughs That Change Patients’ Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to



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