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: December 19, 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 [X] Form 40-F [ ]

On December 19, 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 December 19, 2024

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: December 19, 2024

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

EXHIBIT 99.1

Valneva Successfully Expands Access to Asia for its Chikungunya Vaccine with Serum Institute of India

Saint-Herblain (France), Pune, (India), December 19, 2024 – Valneva SE ("Valneva" or "the Company"), a specialty vaccine company, and Serum Institute of India (SII), the world's largest manufacturer of vaccines by number of doses, today announced an exclusive license agreement for Valneva's single-shot chikungunya vaccine that enables supply of the vaccine in Asia. The collaboration to support broader access to the vaccine in low-and-middle-income countries (LMICs) in the region falls within the framework of the $41.3 million funding agreement Valneva signed with the Coalition for Epidemic Preparedness Innovations (CEPI) in July 2024 with co-funding from the European Union[1].

The companies will work urgently to bring the vaccine to the Indian market, and certain other Asian countries, subject to local regulatory approvals, as India is currently enduring one of its worst chikungunya outbreaks. Nearly 370,000 cases were confirmed in India between January 2019 and July 2024, a number rapidly increasing due to the current outbreak[2].

Under the agreement, the Companies will conduct a technology transfer of the current drug product manufacturing process. Valneva will supply its chikungunya vaccine drug substance to SII, which will complete manufacturing and be responsible for seeking and maintaining regulatory approval of the vaccine in India and other countries in Asia. Future commercialization will be based on a profit-sharing model along with single-digit million milestone payments towards technology transfer and regulatory approvals to Valneva.

Thomas Lingelbach, Chief Executive Officer of Valneva, commented, "The current outbreak in India underscores the fact that containing chikungunya is an international public health priority. SII has extensive manufacturing and commercialization infrastructure and broad market reach in the Asian territory. We are very pleased to enter into this collaboration to help address this urgent medical need by accelerating further access to our highly differentiated vaccine."

Adar Poonawalla, CEO of Serum Institute of India, said, "We are pleased to collaborate with Valneva to bring this chikungunya vaccine to India and other parts of Asia. This collaboration reflects our focus on providing effective and accessible vaccines to address pressing public health needs."

SII, Valneva and CEPI are committed to enabling equitable access to chikungunya vaccine doses manufactured and licensed by SII for the region.

Under the terms of the agreement, SII has committed to priority supply of the chikungunya vaccine at an affordable price to public health markets in LMICs.

SII will also make available a stockpile of 100,000 doses of the drug product to CEPI as an 'investigational ready reserve' that could be used in clinical trials in the region. Such research could provide additional data on the performance of the vaccine among local populations.

A safety stock of up to 100,000 doses of the chikungunya vaccine will also be made available and directly accessible to CEPI, at costs incurred by CEPI, for potential use when responding to a future chikungunya outbreak in the region.

Dr Richard Hatchett, CEO of CEPI, said: "Chikungunya continues to pose a troubling and debilitating danger to the world, including in Asia, with climate change threatening to worsen its spread. Today's new collaboration is a historic achievement which provides a crucial launchpad for the manufacture of a chikungunya vaccine in Asia, for Asia, while also enhancing regional health security and guaranteeing the priority supply of affordable doses to local populations most in need."

Valneva's chikungunya vaccine is the world's first and only licensed chikungunya vaccine, currently approved in the U.S.[3], Europe[4], and Canada[5] for the prevention of disease caused by the chikungunya virus in individuals 18 years of age and older. Regulatory reviews to expand the age range to individuals 12 years of age and older are currently ongoing[3][4]

Supported by CEPI and the European Union (EU)'s Horizon program, Valneva remains focused on expanding the vaccine's access in LMICs. Under an earlier funding agreement with CEPI[5], Valneva partnered with Brazil's Instituto Butantan (IB) to expand access to the vaccine in the Americas. Review of the marketing authorization application by the Brazilian Health Regulatory Agency (ANVISA) is ongoing.

About Chikungunya

Chikungunya virus (CHIKV) is a mosquito-borne viral disease spread by the bites of infected *Aedes* mosquitoes which causes fever, severe joint and muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can persist for weeks to years[6].

In 2004, the disease began to spread quickly, causing large-scale outbreaks around the world. Since the re-emergence of the virus, CHIKV has now been identified in over 110 countries in Asia, Africa, Europe and the Americas[7]. Between 2013 and 2023, more than 3.7 million cases were reported in the Americas[8] and the economic impact is considered to be significant. The medical and economic burden is expected to grow with climate change as the mosquito vectors that transmit the disease continue to spread geographically. As such, the World Health Organization (WHO) has highlighted chikungunya as a major public health problem.[9]

About Valneva SE
We are a specialty vaccine company that develops, manufactures, and commercializes prophylactic vaccines for infectious diseases addressing unmet medical needs. We take a highly specialized and targeted approach, applying our deep expertise across multiple vaccine modalities, focused on providing either first-, best- or only-in-class vaccine solutions.
We have a strong track record, having advanced multiple vaccines from early R&D to approvals, and currently market three proprietary travel vaccines, including the world's first and only chikungunya vaccine, as well as certain third-party vaccines.
Revenues from our growing commercial business help fuel the continued advancement of our vaccine pipeline. This includes the only Lyme disease vaccine candidate in advanced clinical development, which is partnered with Pfizer, the world's most clinically advanced Shigella vaccine candidate, as well as vaccine candidates against the Zika virus and other global public health threats. More information is available at www.valneva.com.

About Serum Institute of India
Serum Institute of India Pvt. Ltd, is a global leader in vaccine manufacturing, dedicated to providing affordable vaccines worldwide. Present across 170+ countries, including the US, UK, and Europe, SII holds the distinction of being the world's largest vaccine manufacturer. SII's multifunctional production and one-of-the-largest facility in Manjri, Pune, with an annual capacity of 4 billion doses, has saved over 30 million lives over the years.

Founded in 1966, SII's primary mission is to produce life-saving immunobiological drugs, with a particular emphasis on affordability and accessibility. Guided by a strong commitment to improving global health, the company has played a pivotal role in reducing the prices of essential vaccines, such as Diphtheria, Tetanus, Pertussis, HIB, BCG, r-Hepatitis B, Measles, Mumps, and Rubella. Notably, they are the manufacturers of 'Pneumosil,' the world's most affordable PCV, 'Cervavac' the first indigenous qHPV vaccine in India, and R21/Matrix-M™, the second malaria vaccine to be authorized for use in children in malaria-endemic regions. Moreover, SII has been at the forefront of the global fight against COVID-19, delivering over 2 billion doses of the COVID-19 vaccine worldwide.

To further expand its global presence and ensure widespread vaccine availability, SII has established Serum Life Sciences Ltd, a subsidiary in the UK. Through relentless pursuit of innovation, SII continues to champion the cause of affordable vaccines, making a positive impact on the lives of millions worldwide

www.seruminstitute.com

About CEPI

CEPI was launched in 2017 as an innovative partnership between public, private, philanthropic and civil organizations. Its mission is to accelerate the development of vaccines and other biologic countermeasures against epidemic and pandemic threats so they can be accessible to all people in need. CEPI has supported the development of more than 50 vaccine candidates or platform technologies against multiple known high-risk pathogens or a future Disease X. Central to CEPI's pandemic-beating five-year plan for 2022-2026 is the '100 Days Mission' to compress the time taken to develop safe, effective, globally accessible vaccines against new threats to just 100 days.

Learn more at CEPI.net. Follow us on X (@CEPIvaccines), LinkedIn and Facebook.

About Horizon Europe
Horizon Europe — #HorizonEU — is the European Union's flagship Research and Innovation programme, part of the EU-long-term Multiannual Financial Framework (MFF) with a budget of €95,5 billion to spend over a seven-year period (2021-2027). Under Horizon Europe, health research will be supported with the aim to find new ways to keep people healthy, prevent diseases, develop better diagnostics and more effective therapies, use personalised medicine approaches to improve healthcare and wellbeing, and take up innovative health technologies, such as digital ones.

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Forward-Looking Statements

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to business partnerships and the progress, timing, results and completion of technology transfer and regulatory approvals in additional markets. In addition, even if the actual results or development of Valneva are consistent with the forward-looking

statements contained in this press release, those results or developments of Valneva may not be sustained in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties and delays involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made in this press release will in fact be realized. Valneva is providing this information as of the date of this press release and disclaims any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

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1 CEPI awards up to US$23.4 million to Valneva for late-stage development of a single-dose chikungunya vaccine
2 https://bluedot.global/vaccines-on-the-table-as-chikungunya-outbreak-intensifies-in-india/
3 *Valneva Submits Label Extension Applications for its Chikungunya Vaccine, IXCHIQ®, to EMA and Health Canada - Valneva*
4 *Valneva Submits Label Extension Application for its Chikungunya Vaccine, IXCHIQ®, to the U.S. FDA - Valneva*
5 *CEPI awards up to $23.4 million to Valneva for late-stage development of a single-dose Chikungunya vaccine*
6 https://jvi.asm.org/content/jvi/88/20/11644.full.pdf
7 https://cmr.asm.org/content/31/1/e00104-16
8 PAHO/WHO data: Number of reported cases of chikungunya fever in the Americas (Cumulative Cases 2018-2023 and Cases per year 2013-2017). https://www.paho.org/data/index.php/en/mnu-topics/chikv-en/550-chikv-weekly-en.html. Last accessed 01 Aug 2023.
9 Geographical expansion of cases of dengue and chikungunya beyond the historical areas of transmission in the Region of the Americas (who.int)