

**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**

**December 20, 2021
Date of Report (Date of earliest event reported)**

DBV Technologies S.A.
(Exact name of registrant as specified in its charter)

France
(State or other jurisdiction
of incorporation)

001-36697
(Commission
File Number)

Not applicable
(IRS Employer
Identification No.)

**177-181 avenue Pierre Brossolette
92120 Montrouge France**
(Address of principal executive offices)

Not Applicable
(Zip Code)

Registrant's telephone number, including area code: +33 1 55 42 78 78

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:

- ☐ 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
Ordinary shares, nominal value €0.10 per share	n/a	The Nasdaq Stock Market LLC*
American Depositary Shares, each representing one-half of one ordinary share, nominal value €0.10 per share	DBVT	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 December 20, 2021, DBV Technologies S.A. issued a press release entitled "DBV Technologies Provides Update on Investigational Viaskin™ Peanut." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated December 20, 2021
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

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 hereunto duly authorized.

Date: December 20, 2021

DBV TECHNOLOGIES S.A.

By: /s/ Sébastien Robitaille

Name: Sébastien Robitaille

Title: Chief Financial Officer



Press Release

Montrouge, France, December 20, 2021

DBV Technologies Provides Update on Investigational Viaskin™ Peanut

DBV Technologies S.A. (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced plans to initiate a new, pivotal Phase 3 clinical study for a modified Viaskin™ Peanut patch in children in the intended patient population. The Company also issued an update on the Marketing Authorization Application for Viaskin Peanut with the European Medicines Agency (EMA).

U.S. Regulatory Update:

DBV has informed the U.S. Food and Drug Administration (FDA) of its intent to initiate a pivotal Phase 3 clinical study for a modified Viaskin Peanut patch in children in the intended patient population. The study will feature the modified Viaskin Peanut (mVP) patch, which is circular in shape and approximately 50% larger than the current Viaskin Peanut (cVP) patch. The mVP outperformed cVP in the healthy adult CHAMP study. The new pivotal study will also include updates to the Instructions for Use (IFU).

DBV received advice and information requests from the FDA concerning the allergen uptake/transport comparability of the mVP to the cVP at the end of November 2021. In review of this communication, it is clear that additional exchanges with the FDA would be needed before DBV could initiate an allergen uptake comparison of mVP and cVP. As previously disclosed, the FDA informed DBV in October 2021 that it would provide additional comments on the STAMP protocol design only after reviewing the data from the allergen uptake/transport comparability study.

After careful review of the FDA's information requests and consideration of all other options, the Company has decided not to pursue the sequential approach to the development plans for Viaskin Peanut (allergen uptake/transport study prior to STAMP) as requested by the FDA in the October 2021 feedback. DBV had planned to run these studies in parallel. DBV estimates that heeding to FDA's newly proposed sequential approach would require at least five rounds of exchanges that necessitate FDA alignment prior to initiating STAMP, a 6-month safety and adhesion study. DBV does not believe this approach to be in the best interest of patients due to the significant time delays associated with FDA review of a resource dependent (non-PDUFA) product.

As such, DBV believes the most efficient way to progress the regulatory pathway for Viaskin Peanut is to conduct a new, Phase 3 placebo-controlled efficacy trial similar to PEPITES (V712-301). DBV considers this approach the most straightforward to demonstrate effectiveness, safety, and improved *in vivo* adhesion of the modified Viaskin Peanut system. The FDA has confirmed DBV's change in strategy is agreeable via oral and written exchanges.



DBV has begun working on a study protocol for the Phase 3 placebo-controlled efficacy trial with mVP and will gain alignment from FDA before initiating the trial. The Company is in the process of finalizing the new, pivotal Phase 3 protocol and expects to submit the protocol to FDA by the end of February 2022.

"DBV is confident that a new, Phase 3 pivotal study generating a robust data set is the best way to support the development of Viaskin Peanut," said Daniel Tasse, Chief Executive Officer, DBV Technologies. "In October, we were surprised to see the FDA request a sequential approach to our development plans. Considering the advice and information requests received by FDA concerning STAMP in October and the allergen uptake/transport study in November, the Company has determined that further exchanges with FDA under resource dependent review timelines are unpredictable, and would likely result in extended delays to our regulatory progress. We believe Viaskin Peanut is a viable treatment option for patients that are currently underserved and eagerly awaiting options. It is our priority to bring a safe, efficacious, and convenient product to them as quickly as possible."

EU Regulatory Update:

DBV Technologies today announced that it has formally notified the European Medicines Agency (EMA) of its decision to withdraw the Marketing Authorization Application (MAA) for Viaskin Peanut. The application for Viaskin Peanut was accepted by the EMA in November 2020. At the time of the withdrawal, it was under review by the EMA's Committee for Medicinal Products for Human Use (CHMP).

The initial filing was supported by positive data from a single, Phase 3 pivotal trial, PEPITES (V712-301). The decision to withdraw was based on the current view of the CHMP that the data available to date from a single pivotal study in the MAA were not sufficient to preclude a Major Objection at Day 180 of the review process. As previously disclosed, the Major Objection focuses on the limitations of the data, for example, the clinical relevance and effect size. DBV believes that generating data from a new, Phase 3 pivotal trial will support a more robust path to licensure for Viaskin Peanut in the European Union.

"DBV's decision to withdraw the MAA for Viaskin Peanut reflects careful consideration in putting the strongest application forward for patients in the European Union," said Pharis Mohideen, Chief Medical Officer, DBV Technologies. "The team has been thoughtful and



analytical in designing a new, Phase 3 pivotal trial protocol to support the U.S. and European regulatory pathways and will continue to work closely with the EMA as we generate additional data. There is a significant need for effective and well-tolerated therapies for those living with peanut allergy, and we are committed to bringing Viaskin Peanut to patients and physicians as quickly as possible.”

DBV will host a conference call and live audio webcast on Monday, December 20, 2021, at 5:00 p.m. ET to provide an update on investigational Viaskin Peanut.

This call is accessible via the below teleconferencing numbers, followed by the reference ID: 50269344.

- United States: (866) 939-3921
- Canada: (866) 215-5508
- United Kingdom: 0808 238 9578
- France: 0805 102 604

A live webcast of the call will be available on the News & Resources section of the Company's website:

<https://www.dbv-technologies.com/news-and-resources/>. A replay of the presentation will also be available on DBV's website after the event.

About DBV Technologies

DBV Technologies is developing Viaskin™, an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT™, DBV's method of delivering biologically active compounds to the immune system through intact skin. With this new class of non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients. DBV's food allergies programs include ongoing clinical trials of Viaskin Peanut. DBV Technologies has global headquarters in Montrouge, France, and North American operations in Summit, NJ. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding DBV's planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, and the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, DBV's product candidates have not been



authorized for sale in any country. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, including the impact of the COVID-19 pandemic. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in DBV's regulatory filings with the French Autorité des Marchés Financiers ("AMF"), DBV's filings and reports with the U.S. Securities and Exchange Commission ("SEC"), including in DBV's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 17, 2021, and future filings and reports made with the AMF and SEC by DBV. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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