UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-36697

DBV TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

France	**Not applicable**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
107 Av. de la République	
92320 Châtillon	
(Address of principal executive offices)	**(Zip Code)**

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

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 five ordinary shares, nominal value €0.10 per share	**DBVT**	**The Nasdaq Stock Market LLC**
Ordinary shares, nominal value €0.10 per share*	**n/a**	**The Nasdaq Stock Market LLC**

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Securities registered pursuant to section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☒ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing price per American Depositary Share ("ADS"), of the registrant's ADSs on The Nasdaq Capital Market on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was $250.9 million.

As of March 25, 2026, the registrant had 296,042,447 ordinary shares, nominal value €0.10 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement (the "Proxy Statement") for its 2026 Combined Ordinary and Extraordinary General Shareholders' Meeting, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Any forward-looking statement involves known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statement. Forward-looking statements include statements, other than statements of historical fact, about, among other things:

- our expectations regarding the timing or likelihood of regulatory filings and approvals, including with respect to our anticipated re-submission of a Biologics License Application, or a BLA, for Viaskin Peanut to the U.S. Food and Drug Administration ("FDA");
- our expectations with respect to an actionable regulatory pathway, including an Accelerated Approval pathway, for toddlers ages 1-3 years-old for Viaskin Peanut patch;
- our expectations regarding initiation of the confirmatory effectiveness study for Viaskin Peanut patch in 1-3 year olds;
- anticipated support for the BLA re-submission for the Viaskin Peanut patch to FDA;
- the timing and anticipated results of interactions with regulatory agencies;
- the design, initiation, timing, progress, results and success of our pre-clinical studies and clinical trials, and our research and development programs;
- the sufficiency of existing capital resources;
- our business model and our other strategic plans for our business, product candidates and technology;
- our ability to manufacture clinical and commercial supplies of our product candidates and comply with regulatory requirements related to the manufacturing of our product candidates;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize Viaskin Peanut and/or our other product candidates, if approved;
- the commercialization of our product candidates, if approved;
- our expectations regarding the potential market size and the size of the patient populations for Viaskin Peanut and/or our other product candidates, if approved, and our ability to serve such markets;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance of Viaskin Peanut and/or our other product candidates, if approved, by physicians, patients, third-party payors and others in the medical community;
- our ability to advance product candidates into, and successfully complete, clinical trials;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional funding;
- expectations with respect to cash runway;
- our future financial performance;
- developments relating to our competitors and our industry, including competing therapies; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, these statements are based on our estimates or projections of the future that are subject to known and unknown risks and uncertainties and other important factors that may cause our actual results, level of activity, performance, experience or achievements to differ materially from those expressed or implied by any forward-looking statement. These risks, uncertainties and other factors are described in greater detail under the caption “Risk Factors” in Part I. Item 1A and elsewhere in this Annual Report on Form 10-K. As a result of the risks and uncertainties, the results or events indicated by the forward-looking statements may not occur. Undue reliance should not be placed on any forward-looking statement.

In addition, any forward-looking statement in this Annual Report represents our views only as of the date of this annual report and should not be relied upon as representing our views as of any subsequent date. We anticipate that subsequent events and developments may cause our views to change. Although we may elect to update these forward-looking statements publicly at some point in the future, we specifically disclaim any obligation to do so, except as required by applicable law. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

RISK FACTOR SUMMARY

The below summary risk factors provide an overview of certain of the risks we are exposed to in the normal course of our business activities. The below summary risk factors do not contain all of the information that may be important to investors, and investors should read the summary risk factors together with the more detailed discussion of risks set forth in Part I, Item 1A, “Risk Factors,” of this Annual Report.

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We may require additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.
- We are limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations.
- We are obligated to develop and maintain a system of effective internal controls over financial reporting. These internal controls may be determined to be not effective, which may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares and ADSs.
- We depend almost entirely on the successful development of our novel Viaskin technology. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Viaskin products.
- Our product candidates have undergone and/or will be required to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we, or our collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.
- In most of our clinical trials, we utilize an oral food challenge procedure intentionally designed to trigger an allergic reaction, which could be severe or life-threatening.
- Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay or prevent our ability to generate revenues.
- If our product candidates are not approved by the FDA, or comparable foreign regulatory authorities, we will be unable to commercialize them in the United States or foreign countries.
- The approval process outside the United States varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain regulatory approval in foreign countries would prevent our product candidates from being marketed abroad.
- Even if we, or our collaborators, obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or they market our products, which could materially impair our ability to generate revenue.
- Any of our product candidates for which we, or our collaborators, obtain regulatory approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.
- If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed.
- Access to raw materials and products necessary for the conduct of clinical trials, for commercialization, if approved, and manufacturing of our product candidates and product, if any, is not guaranteed.
- Relying on third-party manufacturers may result in delays in our clinical development or commercialization efforts.
- We rely, and will rely in the future, on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.
- Even if collaborators with which we contract in the future successfully complete clinical trials of our product candidates, those candidates may not be commercialized successfully for other reasons.

- Currently, we do not have commercial-ready marketing and sales infrastructure. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.
- Our product candidates are regulated as biological products, or Biologics, which may subject them to competition sooner than anticipated.
- Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.
- Changes in regulatory requirements, or guidance from the FDA and foreign regulatory authorities or unanticipated events during our clinical trials of Viaskin patch products may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, and could result in increased costs to us and could delay our development timeline.
- If we do not secure collaborations with strategic partners to test, commercialize and manufacture certain product candidates, we may not be able to successfully develop products and generate meaningful revenues.
- Our ability to compete may decline if we do not adequately protect our proprietary rights.
- Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.
- We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.
- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could negatively affect our operating results and business.
- Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our results of operations.
- We may be forced to repay conditional advances prematurely if we fail to comply with our contractual obligations under the applicable innovation grant agreements.
- We will need to develop and implement sales, marketing and distribution capabilities before we are able to bring any product candidate to market, if approved, and as a result, we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
- If we are not able to comply with the applicable continued listing requirements or standards of the Nasdaq Capital Market (“Nasdaq”) our ADSs could be delisted.
- The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of the ADSs.

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Unless the context otherwise requires, we use the terms “DBV,” “DBV Technologies,” the “Company,” “we,” “us” and “our” in this Annual Report on Form 10-K, or Annual Report, to refer to DBV Technologies S.A. and, where appropriate, its consolidated subsidiaries. “Viaskin” and our other registered and common law trade names, trademarks and service marks are the property of DBV Technologies S.A. or our subsidiaries. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

PART I

Item 1. Business.

Overview

DBV Technologies is a late-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin. Our therapeutic approach is based on epicutaneous immunotherapy, or EPIT, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin, an epicutaneous patch (i.e., a skin patch). We have generated significant data demonstrating that Viaskin patch's mechanism of action is novel and differentiated. Viaskin patch targets antigen-presenting immune cells in the skin, called Langerhans cells, that capture the antigen and migrate to the lymph nodes in order to activate the immune system without passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to treat children suffering from food allergies for whom safety is paramount since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as anaphylactic shock. We believe Viaskin technology may offer convenient, non-invasive immunotherapy to patients.
Our most advanced product candidate is Viaskin® Peanut Patch, which has been evaluated as a potential therapy for children with peanut allergy in twelve completed clinical trials, including five Phase 2 trials and five completed Phase 3 trials.

The Company plans a BLA submission in the first half of 2026 for Viaskin Peanut Patch as a potential treatment for children four to seven years old. The Company also has an ongoing Phase 3 supplementary safety study of Viaskin Peanut patch in peanut-allergic toddlers ages one through three. Conditional on successful completion of this safety study, the Company plans a BLA submission in the second half of 2026 for children ages one to three.

The Company has earlier-stage food allergy programs including Viaskin Milk and other autoimmune inflammatory diseases.

Our Strategy

Our goal is to change the field of immunotherapy by developing and commercializing safe, effective, and convenient therapies for patients with food allergies and other immunological conditions. Key elements of our strategy are:

- pursue the continued development of Viaskin® Peanut Patch for toddlers and children with peanut allergy;
- seek regulatory approval for Viaskin® Peanut Patch in the United States and the European Union;
- advance the clinical development of additional Viaskin® product candidates in the United States and other major markets;
- build a broad immunotherapy product pipeline with our innovative Viaskin® technology platform.

The U.S. Commercial Opportunity

The Company is developing launch plans, subject to FDA approval of our product candidate, that are focused on addressing the unmet needs of patients, their caregivers, physicians, and payers. It is estimated that there are approximately 670,000 children ages 1 to 7 years old in the U.S. with peanut allergy. The parents and caregivers for these children are largely part of the millennials demographic which comprises 7.2 million people born between the years of 1981 and 1996. We believe the majority of millennials turn to digital spaces for health information and advice. If VIASKIN Peanut Patch is approved, the Company plans to launch digital and social-media campaigns to activate these parents and caregivers by encouraging shared-decision making conversations with their child's allergist. There are approximately 4,500 allergists in the U.S. and anticipate that a 50 to 70 person specialty sales force can deliver in-person promotional activities to 90% of those physicians. Market research suggests nearly 60% of peanut allergic children are cared for by allergists. In addition, there are approximately 60,000 pediatricians that we anticipate engaging through non-personal promotion. Finally, approximately 50 payers in the U.S. cover 85% of insured lives and that a team of 8 to 10 account managers can be deployed to build strong managed care access.

Peanut Allergy

Unmet Medical Need

Peanut allergy is one of the most common food allergies globally with an overall prevalence across all age groups of approximately 1%, which increases up to 2% in the pediatric population. Based on a 2018 publication, an estimated 2.2% of the pediatric population in the United States, approximately 1.6 million children, is allergic to peanuts. This reflects an increasing prevalence, as has been shown by several epidemiologic studies, including a cross-sectional survey-based study in the United States in which the prevalence of peanut allergy more than tripled between 1997 and 2008 from 0.4% to 1.4%. Studies indicate that most children do not outgrow their peanut allergy, with resolution occurring in only about 20% of young children, making this allergy a life-long affliction in most cases.

Clinically, an allergic reaction to peanut is characterized by rapid onset of symptoms which are triggered by the release of mediators from mast cells and basophils and typically involves one or more target organs. Presentation and severity of allergic reactions are unpredictable and may vary from mild to severe (anaphylaxis) within populations and within individuals over time. In the case of peanut allergy, all individuals are considered at risk for severe allergic reactions, irrespective of their past history.

Current Challenges in the Management of Peanut Allergy Patients

The standard of care for the management of peanut allergy is strict allergen avoidance and the use of epinephrine in case of an allergic reaction. However, since peanut is a common ingredient in many foods, complete avoidance is difficult to achieve, and accidental exposures in peanut-allergic children remains a common issue. The estimated rate of accidental peanut exposure in peanut-allergic children is estimated to be 12.4% per year, with

approximately 40% of children experiencing an accidental exposure within three years of diagnosis. In addition, the constant vigilance required to avoid allergen exposure can affect the quality of life of peanut-allergic children and their parents/caregivers. Daily family activities and social events are negatively impacted by the anxiety and fear of accidental peanut ingestion. According to a 2020 publication, a survey conducted across eight European countries reported high rates of frustration, stress and isolation in peanut-allergic individuals and their caregivers. The current management of peanut allergy has significant limitations and highlights the need for safe and effective treatments that can induce clinical desensitization (i.e., increased tolerance to peanut allergen), thus minimizing the risk of reaction due to accidental ingestion.

Current and Emerging Peanut Allergy Treatments

Several non-specific and allergen-specific treatment approaches are in various stages of clinical development for the treatment of peanut allergy. Food allergen-specific approaches include EPIT, oral immunotherapy ("OIT"), (both with and without adjunctive therapies), and sublingual immunotherapy ("SLIT"). EPIT is an emerging therapeutic approach to food allergy that utilizes the unique immune properties of the skin to deliver allergen directly to antigen-presenting cells in the epidermis and dermis to induce desensitization. Although efficacious, peanut OIT may not be suitable or a preferred option for all children with peanut allergy because of its relatively high rate of systemic side effects and the limitations the treatment places on activities of daily living, including exercise, and unpredictability of tolerance in the setting of intercurrent illness. A proprietary form of OIT, Palforzia®, is approved in the US and the European Union for the treatment of peanut allergy in children aged 1–17 years. In December 2025, Stallergenes Greer, which currently commercializes Palforzia, announced that the product will be discontinued on July 31, 2026, for business reasons. In February 2024, Xolair® (omalizumab), an anti-immunoglobulin E ("IgE") antibody, was approved by the FDA for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. SLIT for peanut allergy has demonstrated evidence of clinical success, with a more satisfactory side effect profile compared to OIT. Despite the evident interest of clinicians to further evaluate these treatment procedures, OIT and SLIT may not be applicable across all ages and risk categories of peanut-allergic children and adults.

Following its acquisition of RAPT Therapeutics in March 2026, GlaxoSmithKline ("GSK") is developing ozureprubart, an IgE-pathway inhibitor with potential relevance for food-allergy treatment. With a Phase IIb readout expected in 2027 and Phase 3 trials planned thereafter, ozureprubart could emerge as a competitor in segments characterized by persistent unmet needs.

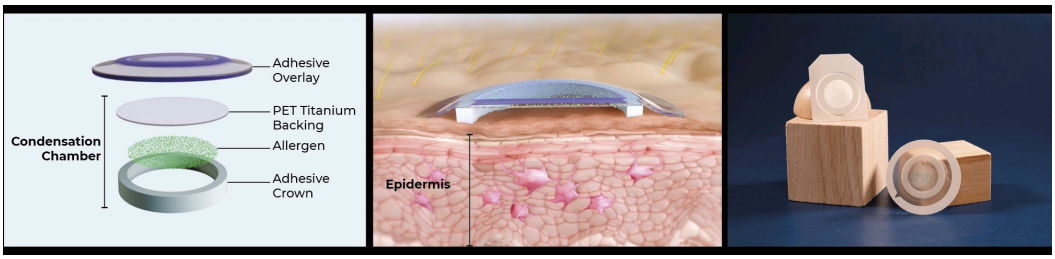
There remains an unmet need for additional therapies for patients with a peanut allergy. In most other therapeutic areas, healthcare providers, patients, and their families have several treatment options, and they are able to choose the treatment that best fits their needs.

Our Viaskin Technology Platform

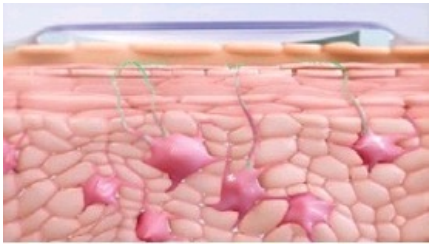
Over the last few decades, we have developed an innovative immunotherapy technology platform, with the potential for sustained therapeutic effect, by delivering biologically active compounds, including antigens, via intact skin. Epicutaneous, also known as on the skin, immunotherapy, or EPIT, exposes tolerance-promoting immune cells in the skin to an adhesive patch containing a small (micrograms) dose of antigen, such as food protein. This technology platform, called Viaskin, is an innovative approach to potentially treating immunological disorders, with a primary focus on food allergy. In EPIT, intact skin is exposed to allergen via the Viaskin technology using a patch that contains microgram amounts of food protein. Allergen applied via EPIT is captured in the superficial layers of the skin by specialized antigen-presenting cells (Langerhans cells within the epidermis), as well as dermal dendritic cells, thus limiting exposure to the bloodstream. In experimental models, EPIT induced a population of regulatory T cells ("Tregs") with specific properties that resulted in suppression of allergic symptoms and protection against further sensitizations. EPIT-induced epigenetic modifications favored a Treg-mediated immune response and a down regulated Th2 response and may play a role in the sustainability of effect. Based on our trials and research, we believe that EPIT has the potential to provide the intended benefits of a disease-modifying treatment in allergy, while avoiding severe or life-threatening allergic reactions.

The key elements of the Viaskin patch mechanism of action, illustrated below, are the following:

- Containing a dry layer of allergen in its center, the patch is positioned on intact skin, without prior preparation.
- The occlusion chamber formed between the skin and the center of the patch promotes an accumulation of water.
- The accumulation of water solubilizes the allergen and allows its passage into the epidermis.



Once in the epidermis, the allergen is captured by a population of highly specialized cells: Langerhans cells. These cells can capture the allergen at the surface of the skin, process it and migrate to the local lymph nodes to present allergen fragments to T-lymphocytes.



Langerhans cells in the epidermis capturing peanut allergen (depicted in green) within the stratum corneum (the outermost layer of the skin) following solubilization of allergen and permeation into the skin after Viaskin patch application.

Our Product Candidates

Our product development strategy is based on leveraging Viaskin's clinical potential. We select our target product candidates with the aim to address allergies that have high unmet medical needs. The following table summarizes the current development status of our product candidates:

Program and Indication	Trials	Phase 2	Phase 3
VIASKIN® Peanut Patch *(DBV712)* - Peanut Allergy	**PEPITES:** Ages 4-11 years → ***PEOPLE:*** *OLE extension to PEPITES (completed)*		●
	REALISE: Ages 4-11 years		●
	VITESSE: Ages 4-7 years → *OLE extension is on-going*		●
	EPITOPE: Ages 1-3 years → ***EPOPEX:*** *OLE extension to EPITOPE (Year 2 of OLE completed)*		●
	COMFORT Toddlers: Ages 1-3 years		◐
VIASKIN® Milk Patch *(DBV135)* – Cow's Milk Allergy (CMA)	**MILES:** Ages 2-17 years	●	
VIASKIN® Milk Patch *(DBV135)* – Eosinophilic Esophagitis (EoE)	**SMILEE:** Ages 4-17 years	●	

● Complete ◐ Ongoing ○ Planned

◦ Phase I and Phase IIb trials of Viaskin Peanut are not included here.

EPIT=epicutaneous immunotherapy; PEPITES=Peanut EPIT Efficacy and Safety Study; PEOPLE=PEPITES Open Label Extension Study; REALISE=Real Life Use and Safety of EPIT; VITESSE=Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy; EPITOPE=EPIT in Toddlers with Peanut Allergy; EPOPEX=EPITOPE Open Label Extension Study.

Viaskin Peanut

Our lead product candidate, Viaskin Peanut, obtained fast track designation and breakthrough therapy designation in children from the FDA, which are regulatory designations intended to expedite or facilitate the process of reviewing new drugs and biological products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition.

We are pursuing two distinct clinical development programs for Viaskin Peanut with two versions of the patch:

- The original square patch (previously called cVP) for toddlers ages 1 - 3 years with peanut allergy.
- A modified circular patch (previously called mVP) for children 4 - 7 years with peanut allergy.

We also have a large supporting dataset from clinical trials of the original square patch in children ages 4 - 11 with peanut allergy.

Viaskin Peanut for Children ages 1-3

We are developing Viaskin Peanut for the treatment of peanut allergy in toddlers one to three years of age, given the high unmet need and the limited number of approved treatments for this population. This program is independent from the Viaskin Peanut Program in 4-7-year-olds and uses the cVP (original patch).

The Viaskin Peanut program for toddlers comprises three Phase 3 clinical trials, with the intent for the trials to support a future BLA submission in this age group:

• EPITOPE (EPIT in Toddlers with Peanut Allergy), a randomized, two-part, pivotal Phase 3 clinical trial assessing the safety and efficacy of Viaskin Peanut for the treatment of peanut-allergic toddlers one to three years of age;

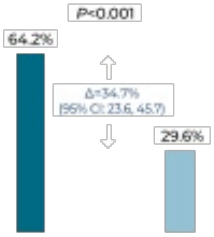
• COMFORT Toddlers (Characterization of the Optimal Management of Food allergy Relief and Treatment), a supplemental safety study to bring the (total) number of subjects on active therapy close to 600 in total when combined with EPITOPE;

• EPOPEX (Phase 3 Open-Label Extension to the EPITOPE Trial), a follow-up of the EPITOPE study to evaluate the long-term efficacy and safety of Viaskin Peanut in very young children.

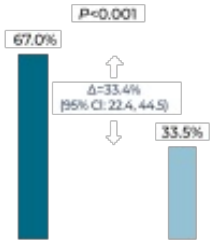
In June 2022, we announced positive topline results from EPITOPE, which enrolled 362 subjects ages 1 to 3 years, of which 244 and 118 were in the active and placebo arms, respectively. Enrollment was balanced for age and baseline disease characteristics between the active and placebo treatment arms. The median subject baseline eliciting dose ("ED") was 100 mg in each treatment arm. A double-blind, placebo-controlled food challenge ("DBPCFC") was administered at baseline and month 12 to determine a subject's ED at each timepoint. A treatment responder was defined as either a subject with a baseline ED ≤10 mg who reached an ED ≥300 mg of peanut protein at month 12, or a subject with a baseline ED >10 mg and ≤300 mg who reached an ED ≥1,000 mg of peanut protein at month 12.

Viaskin Peanut demonstrated a statistically significant treatment effect (p<0.001), with 67.0% of subjects in the Viaskin Peanut arm meeting the treatment responder criteria after 12 months, as compared to 33.5% of subjects in the placebo arm (difference in response rates = 33.4%; 95% the lower bound of the 95% confidence interval ("CI") for the difference in response rates between the active and placebo groups was 22.4%, exceeding the predefined threshold of 15%); left hand side chart. In addition, the proportion of subjects achieving an ED of ≥1000 mg (equivalent to approximately three peanuts) after one year of treatment with Viaskin Peanut 250 µg ("VP250") was significantly increased relative to placebo (64.2% versus 29.6%; p<0.001, right hand side chart).

ED ≥ 1,000 mg



Treatment Responders †



† Responder definition = If eliciting dose (ED) ≤10 mg at baseline, a subject is deemed a responder if ED ≥300 mg at M12. Alternatively, if ED >10 mg and <300 mg at baseline, a subject was deemed a responder if ED ≥1000 mg at M12.

The EPITOPE safety results were generally consistent with the safety profile of Viaskin Peanut 250 µg observed in children with peanut allergy ages 4 years and older in prior clinical trials. No imbalance in the overall adverse event ("AE") rate was observed in the trial between the active and placebo arms.

Overall, 21 subjects (8.6%) in the Viaskin Peanut arm and three subjects (2.5%) in the placebo arm experienced a serious adverse event ("SAE"). Only one of the SAEs (0.4%), which was mild periorbital edema (swelling around the eye) in the Viaskin Peanut arm, was deemed related to treatment. The most commonly reported adverse events were skin reactions localized to the administration site, the majority of which were mild to moderate in nature.

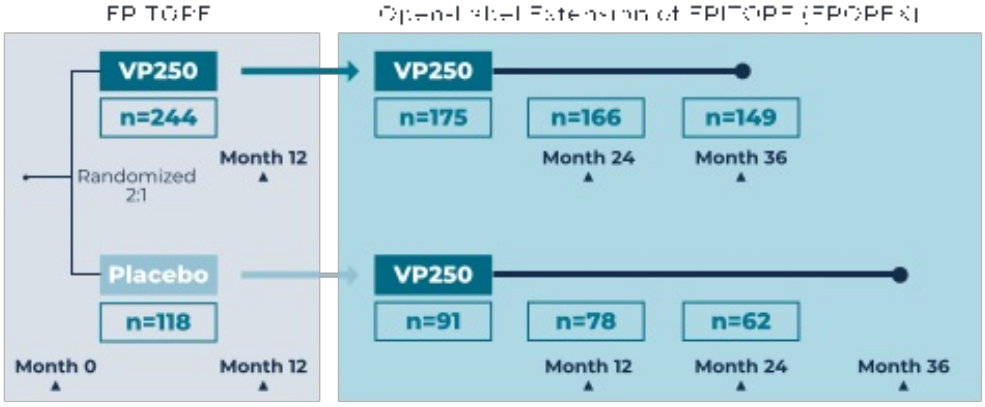
Fifty-five subjects (22.5%) in the Viaskin Peanut arm experienced an application site reaction that was assessed as severe by an investigator compared with 10 subjects (8.5%) in the placebo arm. Based on investigators' reported observations from examinations of the skin at each study visit, using the skin grading systems defined in the protocol, the severity of administration site skin reactions following patch application decreased throughout the course of the 12-month treatment period. Four (1.6%) subjects in the Viaskin Peanut arm experienced an anaphylactic reaction determined to be related to, or possibly related to, treatment. Among these anaphylactic reactions, three resolved with a single dose of epinephrine and one resolved without epinephrine. All anaphylactic reactions were mild to moderate in severity and were characterized mainly by skin and respiratory symptoms.

Eight subjects (3.3%) in the Viaskin Peanut arm discontinued due to adverse events. In the 12-month treatment period, the trial completion rate was 84.8% and was balanced between the Viaskin Peanut and placebo arms. Mean subject compliance to daily patch treatment was above 95% in both the active and placebo arms.

On May 10, 2023, the New England Journal of Medicine (“NEJM”) published results from the EPITOPE phase 3 clinical study that demonstrated EPIT with Viaskin Peanut was statistically superior to placebo in desensitizing children to peanut exposure by increasing the peanut dose that triggers allergic symptoms. As stated in an accompanying editorial piece, these data are seen as “very good news” for toddlers with peanut allergy, as there are currently no approved treatment options for peanut-allergic children under the age of 4 years.

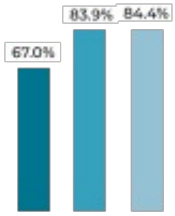
Results from Open-label Extension to EPITOPE Study (EPOPEX)

Following the 12-month treatment period of EPITOPE, eligible subjects could opt to enroll in the open-label, extension (“OLE”) study for up to three years of active total treatment. This ongoing, OLE to EPITOPE is known as EPOPEX and is evaluating the long-term clinical benefit of Viaskin Peanut in subjects who completed the Phase 3 EPITOPE trial. Subjects randomized to active treatment in EPITOPE could receive an additional two-years of treatment in the OLE and subjects randomized to placebo in EPITOPE cross-over to receive three years of active treatment with annual DBPCFC and safety assessments. 266 eligible EPITOPE participants enrolled in EPOPEX.

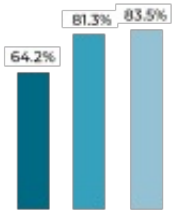


244 underwent the month-24 DBPCFC (n=166 subjects treated with Viaskin Peanut 250 µg for 24 months); 78 subjects originally randomized to the placebo arm of EPITOPE who crossed-over and received active treatment with Viaskin Peanut for one year in the OLE. In November 2023, we announced the interim analyses from the first year of the open-label extension of EPITOPE. These data were presented at the annual American College of Allergy, Asthma, and Immunology (“ACAAI”) in November 2023. Using the same primary endpoint definition that was used in EPITOPE, 83.9% of subjects who completed the DBPCFC met the responder criteria after 24 months. This compares to 67% of subjects after one year of therapy. 81.3% of Viaskin Peanut subjects reached an ED of ≥1000 mg (equivalent to approximately three peanuts; central chart), relative to 64% after one-year of treatment observed in EPITOPE. Furthermore, following an additional year of treatment, 55.9% completed the food challenge without meeting the stopping criteria (i.e., consumed the equivalent of about 12-14 peanuts).

Treatment Responders †



*ED ≥ 1,000 mg



Completed DBPCFC without Meeting Stopping Criteria

- Number of subjects with non-missing food challenge endpoint

Greenhawt et al. EPOPEX, Efficacy and Safety of Epicutaneous Immunotherapy in Peanut-allergic Toddlers: 1-year Open-Label Extension to EPITOPE. Oral Presentation at ACAAI Meeting Nov 2023.

† Responder definition = If eliciting dose (ED) ≤10 mg at baseline, a subject was deemed a responder if ED ≥300 mg at M12. Alternatively, if ED >10 mg and <300 mg at baseline, subject was deemed a responder if ED ≥1000 mg at M12.

* 100 mg = Median ED at Baseline (month 0); *125 mg = Median dose consumed at accidental consumption of peanut (Deschildre A, et al. Clin Exp Allergy 2015; Peanut-allergic patients in the MIRABEL survey: characteristics, allergists' dietary advice and lessons from real life. 46:610-620).

‡ Number of subjects with non-missing food challenge endpoint.

Regarding safety and tolerability findings, no new safety signals were observed, and findings were generally similar to what was reported during the first year of treatment with Viaskin Peanut in EPITOPE. Local application site reactions continued to be the most reported adverse event, with frequency decreasing during the second year of treatment. The frequency of treatment related treatment-emergent advese events ("TEAEs") also decreased in Year 2 relative to Year 1. There were no treatment related serious TEAEs reported during the second year of treatment (versus 1% in EPITOPE). As observed during the first year of treatment with Viaskin Peanut, no TEAEs led to permanent study treatment discontinuation. Finally, no treatment-related anaphylactic events were observed in the second year of treatment (compared with 1.7% of participants during the first year of treatment with Viaskin Peanut in EPITOPE). In summary, two years of VP250 in 1-3-year-old peanut-allergic toddlers resulted in continued increases in treatment effect, beyond those observed after one year, without any new safety signals.

In placebo-treated EPITOPE participants, outcomes after 12 months of cross-over to Viaskin Peanut in EPOPEX were consistent with EPITOPE treatment results: 68.0% were responders (compared to 67% of subjects on active treatment in the first year of EPITOPE); 62.7% of subjects reached an ED ≥1000 mg (relative to 64.2% in EPITOPE); 36.5% reached an ED ≥2000 mg (relative to 37% in EPITOPE); 28.4% completed the DBPCFC without meeting stopping criteria (relative to 30.7% in EPITOPE). There was one event of treatment-related anaphylaxis in Year 2.

We announced month 36 results in January 2025. 266 EPITOPE participants enrolled in the open label extension (EPOPEX) and 211 participants underwent the Month 36 DBPCFC (n=149 VP250; n=62 placebo). After three years of VP250, 83.5% of participants reached an ED of ≥1000 mg, an increase from 64.2% at month 12 (the EPITOPE study). A similar increase was observed for participants reaching an ED of ≥2000 mg (72.7% at month 36; 37.0% at month 12). Those completing the DBPCFC without meeting stopping criteria increased to 68.2% at month 36 from 30.7% at month 12. Continued reductions in DBPCFC reaction severity occurred, with 66.5% having no/mild symptoms at month 36 vs 40.2% at month 12. No treatment-related anaphylaxis or serious treatment-related TEAEs occurred in Year 3. Local application-site reactions occurred less frequently in Year 3 vs Years 1 and 2. In placebo-treated EPITOPE participants, outcomes after 24 months of VP250 in the OLE were consistent with 24-month results in EPITOPE VP250 participants.

Supplemental Safety Study in Toddlers (COMFORT Toddlers)

In April 2023, we received pre-BLA Type B Meeting Written Responses from the FDA related to the Viaskin Peanut program in toddlers. The FDA did not request an additional efficacy study in 1-3-year-olds (i.e., the Agency agreed that the primary endpoint was satisfactorily met in DBV's Phase 3 trial EPITOPE). There was agreement with the FDA to conduct a supplemental safety study using the original square ("cVP") Viaskin Peanut patch to augment the safety data collected from EPITOPE and have close to 600 total subjects on active treatment in the controlled safety database ("COMFORT Toddlers").

On November 9, 2023, the Company submitted the protocol for its COMFORT Toddlers supplemental safety study in 1 – 3 years-old to FDA. The Company received comments and queries to the protocol from the FDA on March 11, 2024.

On October 22, 2024, the Company announced positive regulatory updates for the Viaskin Peanut patch in the United States and Europe. DBV has agreed to guidance provided by the FDA on a potential pathway under the Accelerated Approval Program for the Viaskin Peanut patch in toddlers ages 1 – 3 years-old. FDA confirmed that the Company has met Accelerated Approval qualifying criteria 1 and 2. Regarding criterion 3, FDA has provided guidance and suggestion regarding the intermediate clinical endpoint, which the Company has agreed to in informal discussions with the FDA. The Company formalized the Accelerated Approval guidance provided by FDA via submission of a meeting request and confirmed the general elements of the two study components: the COMFORT Toddlers safety study, to be completed before BLA submission, and the confirmatory effectiveness study, including the third Accelerated Approval criterion regarding the intermediate clinical endpoint. The Company expects that the confirmatory study will be initiated by the time of BLA submission and would run in parallel to commercialization in the United States, if the Viaskin Peanut patch is approved.

The Company announced further that it has aligned with FDA on a wear time collection methodology in COMFORT Toddlers that provides a practical approach for subjects and families, is intended to generate sufficient data to support a BLA submission, and places wear time into an acceptable clinical hierarchy relative to other study endpoints. On June 25, 2025, the Company announced that the first subject was screened in COMFORT Toddlers supplemental safety study in peanut allergic toddlers 1 – 3 years old. The Company anticipates enrolling approximately 300 – 350 subjects on active treatment into the COMFORT Toddlers safety study, which would bring the total Viaskin Peanut patch safety database in toddlers to approximately 600 subjects, consistent with prior FDA guidance. With this path forward, the BLA submission for Viaskin Peanut patch in 1 – 3 years-old under the Accelerated Approval program is anticipated to be supported by:

i. Positive efficacy and safety data from DBV's previously completed EPITOPE Phase 3 Study; and

ii. Additional safety data generated in COMFORT Toddlers supplemental safety study to be initiated in the second quarter of 2025.

On December 11, 2024, the Company announced that it reached alignment with FDA on the Accelerated Approval pathway for Viaskin Peanut patch in toddlers 1-3 years-old and on key study design elements for the COMFORT Toddlers study, including study size and wear time collection methodology and analysis. The Company announced further that FDA confirmed criteria for a post-marketing confirmatory study in toddlers 1-3 years-old and that the Company and FDA agreed that the confirmatory study will assess the effectiveness of the intended commercial Viaskin Peanut patch and will need to be initiated at the time that the BLA is submitted.

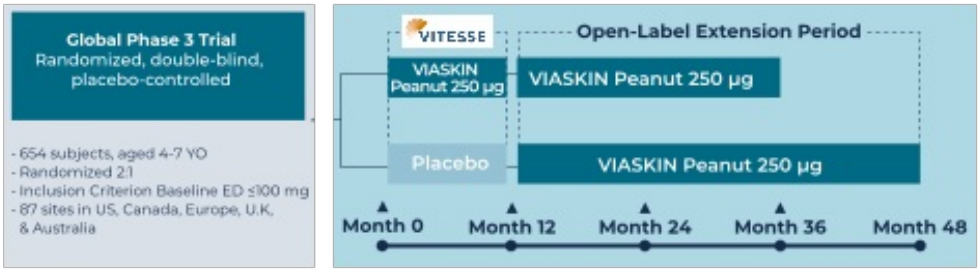
Viaskin Peanut for Children ages 4-7

We are evaluating the modified (circular) Viaskin Peanut patch in children ages 4-7 years with peanut allergy in two Phase 3 clinical trials with the intent for the trials to support a future BLA submission in this age group.

VITESSE (Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy)

On September 7, 2022, we announced the initiation of VITESSE, a new Phase 3 pivotal study of the modified Viaskin Peanut ("mVP") patch in children ages 4-7 years with peanut allergy. We defined initiation as the submission of the trial protocol to selected study sites for subsequent Institutional Review Board ("IRB") approval and Ethics Committee (EC) opinion.

On September 21, 2022, the Company announced it received from the FDA a partial clinical hold letter related to certain design elements of VITESSE. The Company announced on December 23, 2022 that the FDA lifted the partial clinical hold. The FDA confirmed the Company satisfactorily addressed all clinical hold issues and the VITESSE phase 3 clinical study could proceed with the revised trial protocol. On March 7, 2023, the Company announced that the first patient was screened in the VITESSE trial. The Company announced on September 23, 2024 that subject screening has been completed in the third quarter of 2024.



We enrolled a total of 654 subjects for participation in the VITESSE study, randomized 2:1 active to placebo. The primary efficacy endpoint is the percentage of treatment responders in the active versus placebo arms at month 12. The primary efficacy analysis was the success criterion of the lower bound of the confidence interval of the difference in responder rates between active and placebo groups being greater than or equal to 15%.

A treatment responder is defined as either a subject with a baseline ED ≤30 mg who reaches an ED ≥300 mg of peanut protein at month 12, or a subject with a baseline ED = 100 mg who reaches an ED ≥600 mg of peanut protein at month 12. A DBPCFC will be administered at baseline and month 12 to determine a subject's ED at both timepoints. We defined the peanut protein sensitivity inclusion criteria to align with peanut allergy patients at the greatest risk of experiencing reactions to accidental peanut ingestion and with the highest unmet need. We added a 600 mg dose of peanut protein to the month 12 DBPCFC to increase the sensitivity of the efficacy assessment.

Participants applied the modified patch (either Viaskin Peanut 250 µg or a placebo) daily for a period of 12 months. The maximum study duration per subject was 58 weeks: a four-week screening period, a 12-month treatment period and a two-week follow-up period. During the screening period, subjects underwent an initial screening visit with assessment for eligibility according to peanut skin prick test ("SPT") and serum peanut IgE.

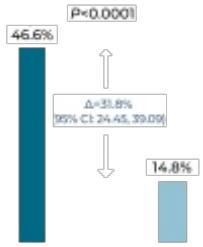
Those meeting these criteria proceeded to a peanut DBPCFC to confirm their peanut allergy and establish an entry peanut ED. The entry DBPCFC was 1 mg peanut protein, and was escalated up to a highest single dose of 100 mg peanut protein. Subjects who reacted with an ED at or below the dose of 100 mg peanut protein were considered eligible. At month 12, a post-treatment DBPCFC was performed, with a starting dose of 3 mg peanut protein, escalating to a highest dose of 1,000 mg peanut protein according to the following schedule: 3, 10, 30, 100, 300, 600, 1,000 mg. Secondary efficacy endpoints included changes in Cumulative Reactive Dose, ED and severity of allergic reaction at baseline and month 12 food challenge. VITESSE also evaluated the safety of the modified Viaskin Peanut patch based on overall adverse events, local site reactions and systemic allergic reactions.

The VITESSE Instructions for Use ("IFU") directed caregivers to apply one patch at approximately the same time each day, following removal of the previous day's patch. The updated IFU outlines that Viaskin Peanut 250 µg is to be worn for as close to a full day as possible (i.e., 24 hours) with a minimum daily wear time of 20 hours each day.

Patch adhesion was assessed in VITESSE to affirm the modified Viaskin Peanut patch performs adequately, which aligns with existing regulatory requirements for patch-based therapies. In post-PCH discussions, we agreed with the FDA that a statistical test of adhesion would be included in the VITESSE statistical analysis plan and further considered patch adhesion data collection and interpretation in the context of the novel nature of the Viaskin patch platform.

On December 16, 2025, the Company announced the positive topline results from the VITESSE study and that its primary endpoint was met. In VITESSE, Viaskin Peanut patch demonstrated a statistically significant treatment effect (p<0.001), with 46.6% of children in the Viaskin Peanut patch arm meeting the treatment responder criteria after 12 months, as compared to 14.8% of children in the placebo arm (difference in response rates = 31.8%; 95% CI = (24.5, 39.0%)), exceeding the lower bound prespecified threshold of 15%. Safety results were consistent with the safety profile of the Viaskin Peanut clinical program to date. The most common TEAEs observed during the VITESSE study were mild-to-moderate local skin reactions at the patch application site. Discontinuations due to TEAEs were low at 3.2% in the treatment arm compared to 0.5% of in the placebo arm. Notably, there were no reports of treatment-related serious adverse events and treatment-related anaphylaxis was low at 0.5% (n=2) and both children continued treatment. The data from the exploratory adhesion assessments were in line with the Company's expectations. Overall, compliance was high at 96.2%, consistent with what has been observed in other Phase 3 Viaskin Peanut studies. The Company is currently conducting the open-label extension phase of the VITESSE study. Following the 12-month double-blind period, participants were given the option to continue into an open-label extension of VITESSE in which all participants receive Viaskin Peanut patch for up to a total of three years on treatment.

VITESSE Primary Endpoint : Percentage of Treatment Responders at M12 (ITT)



Viaskin Peanut for children ages 4-11

Viaskin Peanut completed a global Phase 3 development program for the treatment of peanut allergic patients four to 11 years of age. The program comprised of the following clinical trials:

• PEPITES (Peanut EPIT Efficacy and Safety Study), a randomized, placebo-controlled pivotal Phase 3 trial investigating the safety and efficacy of Viaskin Peanut 250 µg in 356 patients after 12 months of treatment.

• REALISE (REAL Life Use and Safety of EPIT), a randomized, placebo-controlled Phase 3 trial designed to generate safety data after six months of blinded treatment, as well as to evaluate the use of Viaskin Peanut 250 µg in routine clinical practice.

• PEOPLE (PEPITES Open Label Extension Study), a long-term, open-label extension trial of Viaskin Peanut 250 µg. In the PEOPLE trial, patients who were randomized and received active treatment during PEPITES received Viaskin Peanut 250 µg for up to four additional years, while patients who received placebo during PEPITES were treated with Viaskin Peanut 250 µg for up to five years.

The results from PEPITES and REALISE formed the basis for our 2019 regulatory submission in the United States, a BLA for the use of Viaskin Peanut in peanut-allergic patients four to 11 years of age. The results from PEPITES, REALISE and PEOPLE formed the basis for our 2020 regulatory submission in the European Union, a Marketing Authorization Application ("MAA") for the use of Viaskin Peanut in peanut-allergic patients four to 11 years of age.

PEPITES (Peanut EPIT Efficacy and Safety Study)

In December 2015, we initiated a pivotal Phase 3 trial designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in children four to 11 years of age suffering from peanut allergy. PEPITES was a global, randomized 2:1, double-blind, placebo-controlled Phase 3 trial, in which 356 pediatric peanut-allergic patients were treated with Viaskin Peanut 250 µg or placebo for 12 months. A new patch was applied each day, and after two weeks, each patch was worn for 24 hours, plus-or-minus 4 hours. During the trial, patients' sensitivity to peanut protein was assessed using a DBPCFC at baseline and again after 12 months of treatment. The DBPCFC was halted once the patient exhibited an objective symptom, as described on a pre-specified scale, thus establishing a subject's peanut reactivity level, also known as the patient's ED. The median baseline reactive dose in PEPITES was 100 mg at baseline.

The primary responder analysis was conducted after 12 months of treatment. For patients with a baseline peanut protein ED equal to or less than 10 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For patients with a baseline ED greater than 10 mg but less than or equal to 300 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 1,000 mg of peanut protein after 12 months of treatment. Secondary endpoints included the change from baseline of mean and median cumulative reactive dose ("CRD") of peanut protein which is used to establish the total quantity of peanut protein consumed during the DBPCFC. Serological markers were also measured at baseline, three, six and 12 months to characterize the immunological changes observed in patients.

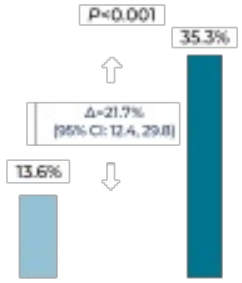
Results of PEPITES Trial

In October 2017, we announced topline results from PEPITES, in which we observed a statistically significant response with a favorable tolerability profile, with (based on "responder" definitions above) 35.3% of patients responding to Viaskin Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates = 21.7%; p=0.00001; 95% CI = 12.4%—29.8%). However, the primary endpoint, which evaluated the 95% CI in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the study's Statistical Analysis Plan submitted to the FDA. The clinical relevance of this is not known. Detailed results were published in *The Journal of the American Medical Association* (JAMA) in February 2019.

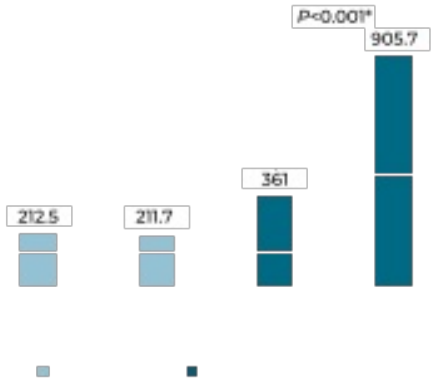
Response Rate (ITT) after 12 months

With respect to CRD, a key secondary endpoint which measures threshold reactivity during the DBPCFC, we observed that at month 12, patients treated with Viaskin Peanut 250 µg or placebo reached a mean CRD of 906 mg (median 444 mg) and 361 mg (median 144 mg) of peanut protein, respectively. Patients in the active and placebo arms entered the trial at similar sensitivity levels; mean CRD at baseline was 211.7 mg (median 144 mg) in the Viaskin Peanut arm and 212.5 mg (median 144 mg) in the placebo arm. A difference in the CRD was observed between Viaskin Peanut and placebo (nominal p-value <0.001) following 12 months of treatment.

Response Rate (ITT) after 12 Months

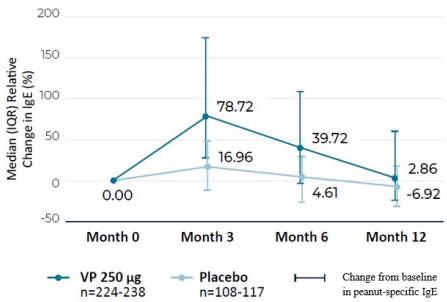


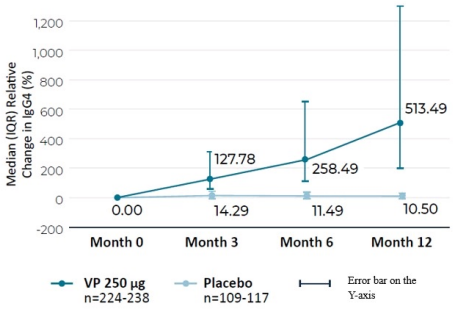
CRD after 12 months



Exploratory analyses showed that changes in peanut-specific biomarkers, including IgE, and immunoglobulin G4 (“IgG4”), support the immunomodulatory effect of Viaskin Peanut. The median observed increase from baseline in peanut-specific IgE was greater in the Viaskin Peanut group vs placebo group, respectively, at month 3 (70.1 kilounits of antibody per liter (“kUA/L”) vs. 9.8 kUA/L) and month 6 (27.4 kUA/L vs. 1.32 kUA/L). However, at month 12, peanut-specific IgE levels were observed to return to near baseline in both groups (1.1 kUA/L vs. -1.1 kUA/L). Median peanut-specific IgG4 were observed to increase over time in the Viaskin Peanut group (change from baseline at month 3: 0.81 mg/L; month 6: 1.79 mg/L; month 12: 3.27 mg/L), while levels remained unchanged from baseline in the placebo group. The change from baseline in peanut-specific IgG4 was greater at all time points with Viaskin Peanut vs. placebo, and the groups were observed to be highly distinguished by this marker, given a flat trend in the placebo arm. These changes are consistent with trends that have been observed with other forms of immunotherapy such as for venom and inhalant allergies.

PEPITES Immunological Responses

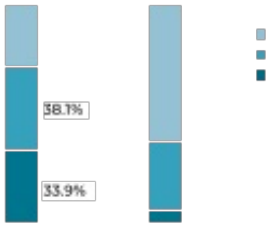




IQR=interquartile range ; **PS**=peanut-specific ; **VP**=Viaskin Peanut.
I. Fleischer DM, et al.JAMA. 2019. doi :10.1001/jama 2019.1113.
II. DBV Technologies, Data on File. February 2019.

In a post-hoc analysis, the majority of subjects on Viaskin Peanut exhibited an increased ED compared to the placebo group (62.6% in active vs. 28% in placebo) at 12 months. An additional post-hoc analysis showed that 53.1% of subjects treated with Viaskin Peanut increased their baseline ED from 100 mg or less to 300 mg or more, compared to 19% in the placebo group. Based on this analysis, we believe that increasing the ED should translate to a reduction in the risk of reaction to accidental peanut exposures, as it will take a higher ingestion quantity to trigger a reaction. Indeed, based on quantitative risk analysis ("QRA") modeling from Baumert et al using national databases of consumption and contamination amounts, this improvement in ED from ≤100 mg to ≥300 mg is predicted to reduce the risk of an allergic reaction due to accidental peanut exposure through a group of common contaminated packaged foods by over 95%.

Change in Eliciting Dose after 12 months



A favorable safety and tolerability profile was observed with Viaskin Peanut. Treatment adherence was high (98.5%), and similar discontinuation rates between treatment groups were reported, with 89.9% of subjects completing the trial. There was a low discontinuation rate due to TEAEs (1.7%), and the overall rate of TEAEs, regardless of relatedness to the treatment, was comparable between treatment and placebo groups, at 95.4% and 89.0%, respectively. The most commonly reported TEAEs were mild to moderate application-site reactions that decreased after month one in both frequency and severity. There were no treatment-related gastrointestinal adverse events or cases of eosinophilic esophagitis in this trial.

There were no cases of severe anaphylaxis in the trial. SAEs were balanced between the Viaskin Peanut and placebo group, at 4.2% vs. 5.1%, respectively. Four SAEs reported in three Viaskin Peanut patients (1.3%) were determined by the investigator as possibly or probably related to treatment. A low rate of treatment-related epinephrine use was reported (2.9% treatment group vs. 0.8% placebo group). Ten cases in eight Viaskin Peanut subjects (3.4%) of possibly or probably treatment-related anaphylaxis occurred, and all were classified as mild or moderate without evidence of cardiovascular, neurologic, or respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight subjects continued on Viaskin Peanut in the trial.

Following the completion of PEPITES, all eligible subjects were invited to enroll in PEOPLE (*Open-Label Follow-Up Study of the PEPITES Study to Evaluate the Long-term Efficacy and Safety of Viaskin Peanut*), a long-term, OLE of Viaskin Peanut 250 µg in children. In the PEOPLE trial, subjects who were randomized and received active treatment during PEPITES received Viaskin Peanut 250 µg for two additional years, while subjects who previously received placebo during PEPITES were treated with Viaskin Peanut 250 µg for three years. In August 2017, we announced the completion of enrollment of the PEOPLE trial, with 298 (92%) subjects who completed PEPITES enrolling in this follow-up trial.

PEOPLE (PEPITES Open Label Extension Study)

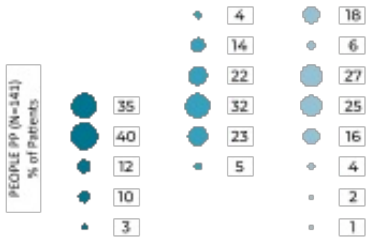
The PEOPLE trial, which was completed in October 2022, is an OLE study that evaluated the long-term safety, tolerability and efficacy of Viaskin Peanut 250 µg in patients who have completed the Phase 3 PEPITES trial. The last patient visit of the PEOPLE trial occurred on October 12, 2022.

In January 2020, we announced positive topline results up to Year 3 from the open-label extension of our Phase 3 PEPITES trial ("PEOPLE") evaluating the long-term efficacy and safety of investigational Viaskin Peanut in peanut-allergic children ages four to 11 years. The results demonstrated long-term clinical benefit as shown by an increase in ED which may decrease the chance of reacting to an accidental peanut exposure. Results of the PEOPLE trial for participants receiving three years of active treatment were published in the *Journal of Allergy and Clinical Immunology* in October 2020.

Of the 356 participants who were enrolled in PEPITES, 298 eligible participants opted to enroll in PEOPLE. Of the 213 patients who were randomized in the active treatment arm of PEPITES and completed the 12-month trial, 198 patients opted to enter the PEOPLE clinical trial (safety population). Of these patients, 148 were considered completers after 36 months and 141 subjects completed all treatment according to the clinical trial protocol without major deviations. Efficacy data were analyzed from these 141 subjects (per protocol).

Topline results from Year 3 of PEOPLE support the long-term tolerability and clinical benefit of Viaskin Peanut, demonstrating desensitization over 36 months of treatment, with 75.9% (107/141) of patients increasing their ED from baseline. After 36 months, 51.8% (73/141) of subjects reached an ED of at least 1,000 mg peanut protein, an increase of 40.4% (57/141) relative to month 12. In addition, 13.5% (19/141) of subjects completed the food challenge without meeting stopping criteria at 36 months (cumulative dose of 5,444 mg). At month 36, the mean CRD was 1,768.8 mg (median 944 mg) compared to 223.8 mg (median 144 mg) at baseline.

% of Subjects (N=141)



Changes in ED were maintained or improved over three years in the majority of subjects in the OLE study (Fleischer DM, et al. *J Allergy Clin Immunol*. 2020;146:863-874).

The safety profile of Viaskin Peanut was consistent with that observed in the clinical program to date in over 1,000 study participants aged 4-11 years old. During the PEOPLE trial, the most common adverse events were mild to moderate skin reactions localized to the administration site, and there was no epinephrine use deemed related to treatment. No treatment related serious adverse events were reported. One subject experienced one case of mild anaphylaxis that was determined by the investigator to be possibly related to treatment and resolved without treatment. Treatment compliance remained high throughout the trial at a mean of 98% over three years of treatment. Low discontinuations due to adverse events were observed, with two children discontinuing the trial due to treatment-related TEAEs during PEOPLE.

Exploratory analyses suggest Viaskin Peanut may offer sustained effect even after a period without treatment. All participants who reached an ED ≥1,000 mg at month 36 were eligible to continue the trial for two additional months without treatment while maintaining a peanut-free diet. A further double-blind placebo-controlled food challenge to determine ED was administered at the end of this period (month 38). The analysis showed that 77.8% (14/18) of the children who completed the oral food challenge at month 38 maintained desensitization with an ED ≥1,000 mg.

REALISE (REAL Life Use and Safety of EPIT)

In November 2016, we initiated a Phase 3 trial in peanut-allergic children four to 11 years of age designed to assess the use and safety of Viaskin Peanut 250 µg in routine clinical practice. REALISE was a multicenter, randomized 3:1, double-blind, placebo-controlled Phase 3 trial, in which pediatric peanut allergic subjects were treated with Viaskin Peanut 250 µg or placebo for six months, followed by an open-label extension period in which all participants were offered up to 36 months total of active treatment. Treatment course with Viaskin Peanut consists of a daily application of the patch on the backs of the patients.

No DBPCFCs were required for entry or during the trial, in order to replicate routine clinical practice. Subjects in the clinical trial were selected, as per clinical practice, based on a well-documented medical history of IgE-mediated reactions to peanut, including children with a history of severe anaphylaxis, along with skin and serum test results highly predictive of peanut allergy. As no DBPCFCs were required, the primary endpoint of the clinical trial was safety as measured by adverse events, TEAEs and SAEs after six months of blinded treatment. Secondary endpoints included evolution of peanut-specific serological markers over time, including IgE, IgG and skin prick test wheal. Exploratory criteria also included scores from subjects' Food Allergy Quality of Life Questionnaire ("FAQLQ") and the Food Allergy Independent Measure ("FAIM").

In March 2017, we announced the completion of enrollment in REALISE, which randomized 393 subjects in 32 centers across North America.

After the initial blinded six-month period, 97.5% of subjects in both the placebo and active arms opted into an open-label portion of the study, which continued monitoring subjects for a total of 36 months of active treatment.

Results of REALISE Trial

Results from the six-month blinded portion of this trial were comparable with outcomes from previous trials of Viaskin Peanut 250 µg. The most commonly reported adverse events were local application site reactions, which were mostly mild and moderate in nature. No imbalance in SAEs was observed in the trial, with three cases in three patients in the active arm (1.0%) and two cases in two subjects in the placebo arm (2.0%). One case in one subject in the active arm was qualified by the investigator as moderate anaphylaxis probably related to treatment. The subject responded to standard outpatient therapy. In the six-month blinded period, the discontinuation rate was 2.5%, with a 1.0% dropout related to adverse events. The mean participant compliance was above 95%.

In November 2021, long-term results of from REALISE, including the safety of Viaskin Peanut over three years and potential impact on health-related quality of life ("HRQL"), were presented at the ACAAI Annual Scientific Meeting.

United States Regulatory History

In August 2019, we announced the submission of a BLA to the FDA for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age.

In August 2020, the Company received a Complete Response Letter ("CRL") in which the FDA indicated it could not approve the Viaskin Peanut BLA in its then-current form. The FDA requested additional Chemistry, Manufacturing and Controls ("CMC") data, but the FDA did not raise any safety concerns related to Viaskin Peanut.

In January 2021, the Company received written responses from the FDA to questions provided in the Type A meeting request that the Company submitted in October 2020 following receipt of the CRL.

In March 2021, the Company commenced CHAMP (Comparison of adHesion Among Modified Patches), a Phase 1 trial in healthy adult volunteers. In May 2021, the Company submitted a proposed protocol to the FDA for STAMP (Safety, Tolerability, and Adhesion of Modified Patches), a 6-month safety and adhesion study which was to be conducted concurrently with DBV's allergen uptake comparison studies (i.e., 'EQUAL in Adults', EQUAL). On October 14, 2021, in an Advice/Information Request letter, the FDA requested the Company conduct a stepwise, or sequential, approach to the modified Viaskin patch development program by conducting EQUAL first and submitting the data for FDA review and feedback prior to starting the STAMP study.

In December 2021, the Company decided not to pursue the sequential approach requested by the FDA and instead announced its plan to initiate a pivotal Phase 3 placebo-controlled efficacy trial for mVP in children in the intended patient population. Following written exchanges with the FDA, the FDA confirmed it had been aligned with the Company's strategy.

On September 7, 2022, the Company announced the initiation of VITESSE, a Phase 3 pivotal study of the mVP in children ages 4-7 years with peanut allergy. On September 21, 2022, the Company announced it received from FDA a partial clinical hold letter related to certain design elements of VITESSE.

On December 23, 2022, the Company announced that the FDA lifted the partial clinical hold. The Company announced on September 23, 2024 that subject screening was completed in the third quarter of 2024. The Company announced the positive topline results from the VITESSE study on December 16, 2025.

On April 19, 2023, the Company outlined the regulatory pathway for Viaskin Peanut patch in children 1-3 years old after the FDA confirmed in written responses to the Company's Pre-BLA meeting request that the Company's EPITOPE phase 3 study met the pre-specified criteria for success for the primary endpoint and did not request any additional efficacy study in this age group. The FDA required additional safety data to augment the safety data collected from EPITOPE in support of a BLA.

On November 9, 2023, the Company submitted the protocol for its COMFORT Toddlers supplemental safety study in 1 – 3 years-old to FDA. The Company received comments and queries to the protocol from the FDA on March 11, 2024. On July 30, 2024, the Company announced that it and the FDA had been engaged in ongoing dialogue since May 2023 on the COMFORT Toddlers supplemental safety study in 1 – 3 years-old with a peanut allergy.

The Company also announced on November 9, 2023, 2-year results from the ongoing phase 3 open-label extension to the EPITOPE trial, EPOPEX, of Viaskin Peanut in toddlers.

On October 22, 2024, the Company announced positive regulatory updates for the Viaskin Peanut patch in the United States and Europe. DBV had agreed to guidance provided by the FDA on a potential pathway under the Accelerated Approval Program for the Viaskin Peanut patch in toddlers ages 1 – 3 years-old. FDA confirmed that the Company met Accelerated Approval qualifying criterion 1 and 2. Regarding criterion 3, FDA provided guidance and suggestion regarding the intermediate clinical endpoint, which the Company agreed to in informal discussions with the FDA. The Company formalized the Accelerated Approval guidance provided by FDA via submission of a meeting request and confirmed the general elements of the two study components: the COMFORT Toddlers safety study, to be completed before BLA submission, and the confirmatory effectiveness study, including the third Accelerated Approval criterion regarding the intermediate clinical endpoint. The Company expects that the confirmatory study will be initiated by the time of BLA submission and would run in parallel to commercialization in the United States, if the Viaskin Peanut patch is approved.

The Company announced further that it aligned with FDA on a wear time collection methodology in COMFORT Toddlers intended to generate sufficient data to support a BLA submission. On June 25, 2025, the Company announced that the first subject was screened in the COMFORT Toddlers supplemental safety study in peanut allergic toddlers 1-3 years old. The Company anticipates enrolling approximately 300 – 350 subjects on active treatment into the safety study, which would bring the total Viaskin Peanut patch safety database in toddlers to approximately 600 subjects, consistent with prior FDA guidance. With this path forward, the BLA submission for the Viaskin Peanut patch in 1 – 3 years-old under the Accelerated Approval program is anticipated to be supported by:

i. Positive efficacy and safety data from DBV's previously completed EPITOPE Phase 3 Study; and

ii. Additional safety data generated in COMFORT Toddlers supplemental safety study to be initiated in the second quarter of 2025.

On December 11, 2024, the Company announced that it reached alignment with FDA on the Accelerated Approval pathway for Viaskin Peanut patch in toddlers 1-3 years-old and on key study design elements for the COMFORT Toddlers study, including study size and wear time collection methodology and analysis. The Company announced further that FDA confirmed criteria for a post-marketing confirmatory study in toddlers 1-3 years-old and that the Company and FDA agreed that the confirmatory study will assess the effectiveness of the intended commercial Viaskin Peanut patch and will need to be initiated at the time that the BLA is submitted.

The Company submitted the protocol for its COMFORT Children supplemental safety study in ages 4-through-7-years-old to the FDA on November 29, 2023. On March 24, 2025, the Company announced that in a Written Responses Only to the Company's Type D investigational new drug ("IND") meeting request the FDA agreed with the Company's proposal that the safety exposure data from the VITESSE Phase 3 study for the Viaskin Peanut patch in 4-7-year-olds will be sufficient to support a BLA filing in this age group. As a result, the COMFORT Children supplemental safety study is no longer required and the Company will not conduct the study. The Company will utilize safety data from VITESSE participants randomized to active treatment as well as placebo-crossover participants in the VITESSE OLE study. Accordingly, the Company plans to submit a BLA for the Viaskin Peanut patch in 4-7 year-olds in the first half of 2026 and anticipates potentially accelerating the product launch by approximately one year, subject to FDA approval.

European Union Regulatory History

In November 2020, we announced that our MAA for Viaskin Peanut, submitted under the name "Abylqis®", had been validated by the European Medicines Agency ("EMA"). The validation of the MAA confirmed that the submission was sufficiently complete to begin the formal review process.

On August 2, 2021, the Company announced it had received from the EMA the Day 180 list of outstanding issues, which is an established part of the prescribed EMA review process, which identified one Major Objection remained at Day 180 questioning the limitations of the data, for example, the clinical relevance and effect size supported by a single pivotal study.

On December 17, 2021, we announced we had withdrawn the MAA for Viaskin Peanut, submitted under the name "Abylqis", and formally notified the EMA of our decision.

On October 22, 2024, the Company announced it received scientific advice from EMA on an indication for ages 1 – 7 years-old in Europe regarding the components of a MAA for the Viaskin Peanut patch. Previous advice obtained from two local country regulatory health authorities indicated a potential path for a 1 – 7 year-old registration with one patch, the modified patch. The EMA recently confirmed through scientific advice that the completed EPITOPE study in 1 – 3 years-old, and a positive VITESSE study in 4 – 7 years-old, could constitute an MAA submission for a 1 – 7 years-old indication for peanut allergy patients using the modified patch, along with a new safety study in toddlers ages 1 – 3 years-old also with the modified patch. Timing for the initiation of this new safety study to satisfy the important EU market is currently being planned.
The Company intends to resubmit the MAA when that data set is available.

Viaskin Milk

Our second product candidate, Viaskin Milk, is in development for the treatment of cow's milk protein allergy ("CMPA") (IgE-mediated) in children two to 17 years of age, and received fast track designation from the FDA in September 2016. In November 2014, we initiated a multi-center, double-blind, placebo-controlled, randomized Phase 1/2 dose-finding trial to study the safety and efficacy of Viaskin Milk in 198 subjects with Immunoglobulin E, or IgE, mediated CMPA, which we refer to as the Milk Efficacy and Safety ("MILES"). The MILES clinical trial was designed to determine a safe and effective dose in two age groups: children ages 2 to 11 and adolescents ages 12 to 17. In June 2015, we announced completion of Part A of the MILES study, or Phase 1, for which the DSMB recommended to continue the trial as planned and did not raise any safety concerns, and we launched Part B, or Phase 2, in October 2015.

In February 2018, we announced topline results from Part B of the MILES study. Following analyses of the data, the 300 µg dose of Viaskin Milk was identified as the dose with the greatest observed clinical activity for children (intent-to-treat ("ITT") p=0.042). We believe these results support further advancement of the Viaskin Milk program, and we intend to discuss findings with regulatory authorities to determine the design of future clinical trial.

Other Applications for the Viaskin Platform

In addition to our development programs in food allergies, we have also explored the use of our Viaskin technology for the treatment of inflammatory and autoimmune diseases with high unmet medical need. Human proof-of-concept trials have been conducted with Viaskin in eosinophilic esophagitis ("EoE") and as a booster vaccination against Bordetella pertussis, or whooping cough, in healthy adults. Our other earlier stage research programs include, in particular, celiac disease.

In May 2016, we entered into a Development Collaboration and License Agreement (the "Collaboration Agreement") with Société des Produits Nestlé S.A. (formerly NESTEC S.A.) ("NESTEC"). The Collaboration Agreement related to an exclusive global collaboration with Nestlé Health Science for the development and, if approved, commercialization of MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of CMPA (non-mediated IgE) in infants.

Under the terms of the Collaboration Agreement, the Company was responsible for leading the development activities of MAG1C up through a pivotal Phase 3 clinical program, and if the appropriate regulatory approvals were received, Nestlé Health Science would support the commercialization of MAG1C globally. The Company was eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, including an upfront payment of €10.0 million received in July 2016.

On October 30, 2023, the Company and NESTEC entered into a Mutual Termination Letter Agreement terminating the Collaboration Agreement. Each party remained responsible for its own costs and expenses related to its respective wind-down activities. Any and all licenses and sublicenses, granted by either party to the other party under the Collaboration Agreement, including, without limitation, any licenses to intellectual property, were revoked and terminated. We may explore selective collaborations with parties who have relevant clinical and commercial expertise in other geographies, including certain European countries and indications outside of food allergies.

Potential Biomarker Applications

We continue to investigate the cellular and molecular mechanisms associated with EPIT, with a particular focus on identifying immunologic biomarkers that may be used to monitor patients' response to Viaskin Peanut. This work is conducted in collaboration with external partners and academic institutions across the United States and EU, and includes the evaluation of serologic (i.e., peanut-specific antibodies) and cellular (e.g., basophil activation) immune parameters, as well as epigenetic modifications, across our clinical development program. As our understanding of the immunologic evolution and epigenetic changes associated with EPIT advances, we believe this research may enable earlier identification of patients who are responding to treatment. Such insights may inform clinical decision-making, support longitudinal clinical follow-up, and assist in evaluating the durability of desensitization following treatment completion.

We have presented and published selected findings from these efforts. At the 2016 EAACI Annual Congress, we reported exploratory analyses of serum biomarkers from in children enrolled in the Phase IIb VIPES trial and its open-label extension. These analyses suggested that a proprietary algorithm integrating selected immunologic variables, including peanut-specific IgE and IgG4, as well as component-resolved measurements, may help monitor patient responses to Viaskin Peanut. Subsequent analyses of serum biomarkers from the Phase 3 PEPITES trial, published in Allergy (Bastin et al., 2023), further characterized the longitudinal evolution of immune parameters. Findings suggested that combining certain serologic markers, including peanut-specific IgG4/sIgE ratios and component-resolved diagnostics (Ara h 1 sIgE), demonstrated moderate discriminative capacity in differentiating clinical responder status after 12 months of treatment. Additional research is planned to further characterize and validate immunologic, cellular, and molecular parameters that may correlate with treatment response. These efforts aim to determine whether such biomarkers, alone or in combination, can be prospectively validated and demonstrate clinical utility in assessing treatment response.

Manufacturing and Supply

Our Proprietary Viaskin Technology

We have engineered a proprietary manufacturing technology for Viaskin patch, which is designed to comply with the most stringent pharmaceutical production standards, including those promulgated by the FDA, in order to enable Viaskin to deliver proteins via intact skin. This novel pharmaceutical process, which was fully developed by us, uses an electrospray to spray homogeneous, thin, dry protein layers onto the Viaskin patch.

This process sprays a liquid solution of electrically charged proteins onto the patch's backing, which is then turned into dry solid charged layers, which remain stuck onto the patch's backing. It deposits very small and precise quantities of the active substance, devoid of adjuvants. The patch can then be stored at room temperature. We believe this patented technology is highly scalable and complies with cGMP requirements.

The principles of the Viaskin electrospray technology are the following:

- A constant flow of liquid in a capillary is subjected to a high voltage electric field.
- With our electrospray machine, we can transform these electrically charged liquid droplets into dry solid layers, deposited onto the patch's backing.
- The electric field directs particles precisely toward the Viaskin patch's backing.

With Viaskin manufacturing technology, we believe we can achieve:

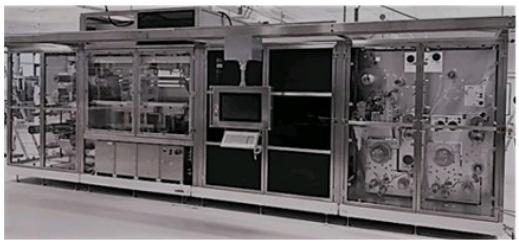
- a homogeneous layer of protein on the Viaskin patch;
- a specific mass of active substance per Viaskin patch;
- an adjustable active substance dosage for clinical trials;
- instant drying of the active substance;
- a high solubility of the active substance; and
- the possibility of spraying on the Viaskin patch both biological and chemical substances.

Viaskin is a Highly Scalable Manufacturing Technology

ES GEN3.3

72 nozzles

Used for patches manufacturing for clinical trials.



ES GEN4.0

288 nozzles

Used for clinical batches and potential commercial products.

Viaskin, a Highly Scalable Manufacturing Technology

Our proprietary Viaskin manufacturing technology is deemed to create high barriers to entry to our line of business, particularly in the engineering and manufacturing of our Viaskin product candidates. We have designed, developed, and built our manufacturing tools, and contracted with third-party manufacturers to operate it.

Development & Potential Commercialization - Sanofi

On August 29, 2025, DBV Technologies S.A. updated its Manufacturing and Supply Agreement (the "Supply Agreement") with SANOFI WINTHROP INDUSTRIE ("SANOFI"), under which SANOFI will manufacture and supply the Viaskin Peanut API exclusively for DBV Technologies S.A. during the agreement term. The Supply Agreement has an effective date of January 1, 2025 and initial term of 4 years with a possibility to extend for an additional period.

This Agreement includes terms related to manufacturing, quality control, pricing, volume commitments, and supply obligations. The Agreement is designed to secure commercial-scale manufacturing capacity in preparation for a potential BLA submission and subsequently, the commercial launch of the Viaskin Peanut patch in the United States.

Development

The Company currently relies on a single contract manufacturer, FAREVA Amboise (“FAREVA”), to manufacture and supply clinical batches of Viaskin® patches. The Company has entered into a Development Services Agreement, dated August 1, 2015, with FAREVA, which sets forth the terms and conditions under which the Company selected FAREVA as its Contract Manufacturing Organization (“CMO”) to implement the production process for Viaskin® patches and to manufacture and supply the Company with batches of finished products for clinical and validation purposes.

Potential Commercialization

We have also entered into a Commercial Supply Agreement, dated January 13, 2020, as amended (the “Commercial Supply Agreement”), with FAREVA setting forth the terms and conditions for the manufacture and supply of commercial batches of Viaskin Peanut by FAREVA. We previously agreed with FAREVA to delay implementation of the Commercial Supply Agreement.

The Company entered into a Services Agreement with FAREVA La Vallée, dated March 18, 2024 (the “PSM Services Agreement”), for the construction of a dedicated production line and the technology transfer from SANOFI for the manufacture of the Peanut Source Material (“PSM”) required for the production of Viaskin Peanut patches .

The PSM Services Agreement also included binding commercial terms related to the manufacture and supply of commercial batches, the main provisions of which were incorporated into that certain Manufacturing and Supply Agreement (“MS Agreement”) effective as of March 17, 2026 between the Company and Fareva La Vallee. setting forth the terms and conditions for the manufacture and supply of PSM by Fareva La Vallee.

Intellectual Property

Our patent portfolio includes pending patent applications and issued patents in the United States and in foreign countries. To date, patents directed to the Viaskin electrostatic patch, as well as patents directed to allergen desensitization methods, have been issued in the major markets, including in particular the United States, Europe, Canada and Australia. We also have patents, extensive know-how and trade secrets covering part of the Viaskin patch manufacturing method using electrospray technology.

These patents and applications generally fall into five broad categories:

- two U.S. patents, which we co-own with Assistance Publique-Hôpitaux de Paris (“AP-HP”) and Université Paris Cité (formerly Université de Paris-Descartes,and prior to that, Université de Paris, prior to merger and name change), relating to the Viaskin electrostatic patch and its use, which expired in 2022;
- patents and patent applications which we own relating to our electrospray method of manufacturing the Viaskin electrostatic patch, which may expire as late as 2029;
- patents and patent applications we co-own with AP-HP, and the Université Paris Cité relating to the treatment of peanut, milk, egg, and other allergies using our Viaskin patch technology, which may expire as early as 2028;
- design patents and patent applications, which we own relating to various designs of components of the Viaskin patch, which may expire as early as 2032; and
- a variety of other patent applications that we own or co-own relating, for example, to uses of the Viaskin patch technology and to treatment of other indications using the Viaskin patch technology, and to other technologies.

U.S. Patent Term Extension and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. Accordingly, if the remaining patent term has fourteen (14) or more years after the FDA approval date, the patent would not be eligible for any patent term extension.

The amount of time by which a patent term may be extended is generally one-half the time between the effective date of an IND submission and the submission date of a BLA plus the time between the submission date of a BLA and the FDA’s approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension. The approval must be the first approval of that product by the FDA, and the application for the extension must be submitted prior to the expiration of the patent, and within 60 days of the FDA’s approval of the product. The U.S. Patent and Trademark Office (“USPTO”) in consultation with the FDA, reviews and approves the application for any patent term extension. In the future, we may apply for extension of patent term for our owned or licensed patents to add patent term beyond its then-current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA. Some foreign jurisdictions have analogous patent term extension provisions that allow for extension of the term of a patent that covers a product approved by the applicable foreign regulatory agency. In the future, if a Viaskin patch receives FDA approval, we expect to apply for a patent term extension on the patent that we believe will provide the best exclusivity position for that product if extended.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”). Biosimilarity requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, which can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a biological product be biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar product based on the reference biological product until four years after the date of first licensure. “First licensure” typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification

changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the “first licensure” of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

Co-Ownership Agreement

AP-HP and Université Paris Cité (formerly known as Université de Paris-Descartes)

In December 2008, we entered into an assignment, development and co-ownership agreement with AP-HP and Université Paris-Descartes, which through a merger and a name change became Université Paris Cité, by which we agreed to terms of co-ownership with AP-HP and Université Paris Cité of certain U.S. and foreign patents and patent applications, referred to herein as the “shared patents.” We, and any licensees or sublicensees that we designate, have the exclusive right to commercial uses of the shared patents. AP-HP and Université Paris Cité agreed to use the shared patents only for internal research purposes and not to license the shared patents to any third party. Upon commercialization of any product covered by the shared patents, which we expect would include our Viaskin product candidates, we will be obligated to pay AP-HP and Université Paris Cité a percentage of net sales as a royalty. This royalty is in the low single digits and varies depending on the particular patent. Additionally, if we license any of the shared patents to a third party and a licensee commercializes products covered by such shared patents, we will be obligated to pay AP-HP and Université Paris Cité a percentage in the low single digits of the money that we receive from our licensee.

If we do not sell any of our product candidates covered by any of the shared patents within 30 months from the date we first market such product candidates, AP-HP may, upon six months’ notice and subject to certain exceptions, convert our exclusive right to the commercial use of the shared patents to a non-exclusive right.

Any party may terminate the assignment, development and co-ownership agreement in the event of another party’s substantial breach which remains uncured after six months of receiving written notice of such breach. The agreement will also terminate in the event we cease operations or are subject to a dissolution or bankruptcy proceedings.

Absent early termination, the assignment, development and co-ownership agreement will automatically terminate upon the expiration, cancellation, or abandonment of the last shared patent. In the event the agreement is terminated early, we would no longer have the exclusive right to commercial use of the shared patents, though we would retain our shared ownership rights. In addition, our ownership stake in certain jointly made improvements covered by, or depending on, at least one of the shared patents would survive termination of the agreement. The longest-lived patent rights under the agreement are currently expected to expire in 2031, absent patent term extension.

Contract Research Organizations (CROs)

The Company engages CROs in the conduct and oversight of clinical trials sponsored by the Company:

Agreement Related to the Phase 3 VITESSE - Clinical Trial with SYNEOS HEALTH France SARL

The Company entered into a work order on September 15, 2022 (the “SYNEOS Work Order”), pursuant to the terms of a Master Services Agreement dated July 15, 2014, as amended (the “SYNEOS MSA”), with SYNEOS HEALTH France SARL (“SYNEOS”) for the initiation of the VITESSE Phase 3 study.

The purpose of this SYNEOS Work Order is to implement all start-up, monitoring, and close-out activities necessary for the conduct of the VITESSE clinical trial through the delivery of the final clinical study report. The SYNEOS Work Order will terminate upon completion of the services described in the SYNEOS Work Order, unless terminated earlier as defined in the SYNEOS MSA.

Agreement Related to the Phase 3 COMFORT Toddlers - Clinical Trial with ICON

The Company entered into a task order, effective as of January 15, 2025, as amended (the “ICON Task Order”), pursuant to the terms of a Master Agreement for Clinical Trials Management Services, dated December 5, 2011 (the “ICON MSA”), with ICON Clinical Research Limited (“ICON”) for the conduct of the COMFORT Toddlers supplemental safety study.

The purpose of the ICON Task Order is to implement all start-up, monitoring, and close-out activities necessary for the conduct of the COMFORT Toddlers clinical trial through the delivery of the final clinical study report. The agreement will terminate upon completion of the services described in the ICON Task Order, unless terminated earlier as defined in the ICON MSA.

Agreement Related to the Phase 3 EPOPEX - Clinical Trial with PRA / ICON

DBV Technologies S.A. entered into a service agreement on May 24, 2018 with ICON, as successor in interest to Pharmaceutical Research Associates, Inc. for the management of the Phase 3 study EPOPEX. The purpose of this agreement was to implement all start-up, monitoring, and close-out activities necessary for the conduct of this clinical trial through the delivery of the final clinical study report.

Agreement Related to planned Phase II Clinical Trial with Advanced Clinical

The Company has entered into a work order, effective November 18, 2025 (the "Advanced Clinical Work Order"), pursuant to a Master Services Agreement, effective March 18, 2025 (the "Advanced Clinical MSA"), with Advanced Clinical LLC ("Advanced Clinical") for the conduct of the Phase II clinical study to assess the efficacy and safety of Viaskin Peanut patch in achieving ad lib consumption of dietary peanut in peanut allergic infants 6 through 12 months of age. The purpose of the Advanced Clinical Work Order is to implement all start-up, monitoring, and close-out activities necessary for the conduct of this clinical trial through the delivery of the final clinical study report.

This Advanced Clincial Work Order expires upon completion of the services, unless terminated earlier as defined in the Advanced Clinical MSA.

Agreement Related to the Expanded Access Program

The Company entered into a statement of work, dated November 10, 2023, as amended (the "EAC SOW"), pursuant to a Master Services Agreement, dated February 21, 2020 (the "EAC MSA"), with Early Access Care LLC ("EAC") for the conduct and management of an expanded access program.

The EAC SOW expires as of December 31, 2026, unless terminated earlier in accordance with the EAC MSA between the two parties December 31, 2026.

Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid change as researchers learn more about diseases and develop new technologies and treatments. Differentiating competitive factors in the pharmaceutical industry include product efficacy and safety; quality and breadth of an organization's technology; skill of an organization's employees and its ability to recruit and retain key employees; timing and scope of regulatory approvals; government reimbursement rates for, and the average selling price of, products; the availability of raw materials and qualified manufacturing capacity; manufacturing and distribution costs; intellectual property and patent rights and their protection; and sales and marketing capabilities.

Our competitors may succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we are able to do, which could place us at a significant competitive disadvantage. Market acceptance of our product candidates will depend on a number of factors, including: (1) potential advantages over existing or alternative therapies or tests; (2) the actual or perceived safety and efficacy of similar classes of products; (3) the effectiveness of selling, marketing, and distribution capabilities; and (4) the scope of any approval provided by the FDA or comparable foreign regulatory authorities.

Although we believe our product candidates possess attractive attributes, we cannot assure you that our product candidate will achieve regulatory or market acceptance, or that we will be able to compete effectively in the biopharmaceutical drug markets. If our product candidates fail to gain regulatory approvals and acceptance in their intended markets, we may not generate meaningful revenues or achieve profitability.

Numerous pharmaceutical and biotechnology companies, universities and other research entities are actively involved in the discovery, development and commercialization of therapeutic options to treat allergies. There are competitors in the food allergy space that have greater resources and experience than we do.

We are aware of several food allergy studies and pharmaceutical developmental efforts connected with such studies that are currently being conducted in major medical centers and hospitals worldwide. These studies are evaluating forms of allergen desensitization treatments such as OIT; SLIT; subcutaneous ("SCIT"); oral mucosal ("OMIT"); cutaneous and intranasal ("INT") immunotherapy, synthetic, denatured allergens, small molecule inhibitors, or combinations of medicines or methods.

Studies combining methods of allergen immunotherapy, such as OIT, with monoclonal antibodies also are being conducted currently. These types of co-administrations may significantly improve the safety of specific allergen immunotherapies administered orally or subcutaneously. In addition, the use of monoclonal antibodies as monotherapy for certain food allergies, including peanut allergy, is being studied in clinical trials. Monoclonal antibodies, used alone or in combination with allergen immunotherapy, may become significant competitors to our products.

There is one treatment for peanut allergy in children 1 to 17 years of age approved by the FDA and the European Commission: Palforzia, a formulation of peanut flour developed by Aimmune Therapeutics, Inc. ("Aimmune"). Nestlé S.A. acquired Aimmune in October 2020 and divested the Palforzia business to Stallergenes Greer in September 2023. In December 2025, Stallergenes Greer announced that it intends to discontinue the commercialization of Palforzia, on July 31, 2026. In addition, Xolair (omalizumab) is approved by the FDA for the reduction of allergic reactions including reducing the risk of anaphylaxis, that may occur with accidental exposure to one or more food allergens, including peanut. Omalizumab is an anti-IgE monoclonal antibody that is administered via subcutaneous injection. The prescribing information for both Palforzia and Xolair indicate patients should continue to avoid all foods to which they are allergic.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and biological products, or biologics, such as our product candidates. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act ("PHSA") and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the BLA process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices ("GCPs") to establish the safety and efficacy of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the pre-clinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or regulatory non-compliance. Accordingly, we cannot be sure that submission of an original IND submission will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or disease-affected subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection (inclusion and exclusion criteria), and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to such protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to participants in a clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to the IRB's, health authorities and public registries (such as clinicaltrials.gov). Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and publicly disclose specified clinical trial information on www.clinicaltrials.gov. Information related to the product candidate, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials, if Phase 1 trials do not reveal unacceptable toxicity, typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of subjects at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the product candidate for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product candidate and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gather information about a product candidate's safety, efficacy, and optimal use from the treatment of subjects in the intended therapeutic indication. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of a clinical trial must be submitted periodically to the FDA. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected

adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements and/or protocol or if the product has been associated with unexpected serious harm to subjects or patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA and FDA Review Process

Following completion of a clinical trial, data generated from such trial is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product candidate and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market a biologic product for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials and positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic product may be marketed in the United States.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual program fee for approved drugs. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first application filed by a small business or for certain products with an Orphan Drug Designation.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's goal is to review such BLA within ten months of the filing date for standard review or six months of the filing date for priority review (if granted by the FDA), if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness compared to other currently approved products for the condition. The review process is often significantly extended by FDA requests for additional information or clarification. If not accepted for filing, the sponsor must resubmit the BLA and begin the FDA's review process again, including the initial sixty-day review to determine if the application is sufficiently complete to permit substantive review.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP to assure and preserve the product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and usually a vote by the members as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the sponsor during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and the sponsor may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the product candidate to determine whether they comply with cGMPs. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product candidate within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than a sponsor interprets the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and a sponsor may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Review and Approval of Combination Products in the United States

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Our Viaskin product candidates are combination products comprising a device for delivery of a biologic product. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product concurrently with the submission of an IND or at any time before a pre-NDA meeting, and the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Unique to a fast track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it treats a serious condition and has the potential to provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as:

- distribution restricted to certain facilities or physicians with special training or experience; or
- distribution conditioned on the performance of specified medical procedures.

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Therapy Designation

The Food and Drug Administration Safety and Innovation Act ("FDASIA"), amended the FDCA to require the FDA to expedite the development and review of a breakthrough therapy. A product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a product candidate be designated as a breakthrough therapy concurrently with the submission of an IND or any time before an end-of-Phase-II meeting, and the FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Pediatric Trials

Under the Pediatric Research Equity Act ("PREA") a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the

product is safe and effective. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

Post-Marketing Requirements

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling, also known as off-label use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. Moreover, the constituent parts of a combination product retain their regulatory status, for example, as a biologic or device, and as such, we may be subject to additional requirements in the Quality Management System Regulation ("QMSR") applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services ("CMS") other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs, among other activities, must also comply with state and federal fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, the exclusion from participation in federal and state healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts, integrity obligations and individual imprisonment. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

European Union Drug Development

In the European Union ("EU") product candidates are also subject to extensive regulatory requirements. Approval from the competent authorities of EU Member States must be obtained before commencing clinical trials. In addition, as in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory authorities has been obtained.

Clinical Trials in the EU

Similar to the United States, the various phases of pre-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization ("ICH") guidelines on GCPs, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No. 536/2014 ("CTR") which entered into application on January 31, 2022, repealing and replacing the Clinical Trials Directive 2001/20 ("CTD"). The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from competent authorities of EU Member States in which the sponsor intends on carrying out clinical trials, and a positive opinion from an independent Ethics Committee. The CTR, which is directly applicable in all EU Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System ("CTIS"). The CTR also establishes a single set of documents to be prepared and submitted for the application including, among other things, a copy of the trial protocol and an Investigational Medicinal Product Dossier ("IMPD") containing information about the manufacture and quality of the medicinal product under investigation, as well as simplified reporting procedures for clinical trial sponsors.

A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference EU Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU Member States. This assessment is then submitted to the competent authorities of all concerned EU Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned EU Member State. Each concerned EU Member State will issue a single decision on the authorization of the clinical trial including input from the national competent authority and Ethics Committee. Individual EU Member States, therefore, retain the power to authorize the conduct of clinical trials in their territory.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

In all cases, clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Medicines used in clinical trials must be manufactured in accordance with the guidelines on cGMP and in a GMP licensed facility, which can be subject to GMP inspections.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization ("MA").

To obtain a MA for a product in the EU, an applicant must submit a MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the EEA. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, autoimmune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP") conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred

to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human ("CMDh") for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the eCTD (Common Technical Document) providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies, are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development

In the EU, Regulation (EC) No. 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which the MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC") if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Post-approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan ("RMP") describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Other EU Compliance Requirements

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU legislation, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Much like the Anti-Kickback Statute prohibition in the United States, described above, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Payments made to physicians and other health care professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with health care professionals may require prior notification or approval by the health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Combination Products

The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product and a medical device may be regulated as either a medicinal product, a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which of the components of the combination has the primary mode of action.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal product is principal to that of the medical device are governed by the regulatory framework applicable to medicinal products. However, the General Safety and Performance Requirements ("GSPRs") of Annex I to Regulation (EU) 2017/745 on Medical Devices ("MDR") will be applicable to the safety and performance of the medical device part of the product in the context of its use with the medicinal product. In these circumstances, an MAA must be submitted to the competent authorities responsible for evaluating the safety and effectiveness of medicinal products. As part of the MAA, the applicant must also submit, where available, the results of the assessment of the conformity of the medical device part of the product with the MDR contained in the manufacturer's EU Declaration of Conformity of the device or the relevant Certificate of Conformity issued by a Notified Body. If the MAA does not include the results of the conformity assessment, and where the conformity assessment of the device, if used separately, requires the involvement of a Notified Body, the competent authorities must require the applicant to provide a Notified Body Opinion on the conformity of the device with the relevant GSPRs. Based on this approach, the competent authorities responsible for medicinal products will review the specific aspects of the medical devices part of the product which are relevant to the safety and efficacy of the medicinal product and the Notified Body – where applicable – will evaluate the relevant GSPRs of the device.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to MDR. However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an EU Member State or from the EMA, depending on its nature and therapeutic intention, must be sought regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where the primary mode of action of the combined product comes from the medicinal product, it is regulated as a medicinal product. .In this case, the medicinal product should also be compliant, in whole or in part, with regulation (EU) 2017/745 and particularly the Article 117. Unless an express waiver is granted, Article 117 requires a Notified Body opinion on the conformity of the device part to the relevant GSPRs of the MDR. An exemption may be granted from the authorities if the request is justified.

Other Regulatory Matters

UK Regulations

The Medicines and Healthcare products Regulatory Agency (“MHRA”) is now the United Kingdom’s (“UK”) standalone regulator for medicinal products and medical devices. The United Kingdom is now a third country to the EU.

While the United Kingdom’s regulatory framework for clinical trials was historically based on the Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the former EU Clinical Trials Directive, this has been significantly reformed by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024. The new legislation, which was adopted in April 2025, modernizes the United Kingdom's approach to make it a more attractive location for research, and includes key features such as: (i) a risk-proportionate approach, including a notification scheme for lower-risk trials; (ii) a combined review process integrating ethics committee and regulatory approvals into a single, streamlined pathway; (iii) enhanced transparency requirements mandating registration of clinical trials in a public registry and publication of trial results within 12 months of trial completion (with scope for deferrals in certain circumstances); (iv) greater flexibility to support innovation in clinical trial design; and (v) measures to promote patient and public involvement. The amendments will become applicable on April 28, 2026 following a one-year transition period.

Marketing authorizations in the United Kingdom are governed by the Human Medicines Regulations (SI 2012/1916), as amended. In order to obtain a United Kingdom MA to commercialize products in the United Kingdom, an applicant must be established in the United Kingdom and must follow one of the United Kingdom national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure (“IRP”), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the United Kingdom. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval hasn’t been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

All existing marketing authorizations of the EU for centrally authorized products were automatically converted or grandfathered into the United Kingdom’s marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, unless the marketing authorization holder opted-out of this possibility. On January 1, 2025, the “Windsor Framework” came into effect and reintegrating Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products and introducing a UK-wide licensing process for medicines.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding marketing authorization application. The criteria are essentially the same as those in the EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Upon the grant of a marketing authorization with orphan status, the medicinal product will benefit from up to 10 years of market exclusivity from similar products in the approved orphan indication. The start of this market exclusivity period will be set from the date of first approval of the product in the UK.

Reimbursement and Reform

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. Sales of our products will depend, in part, on the extent to which our products, once approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, sponsors may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. For example, the U.S. Department of Health and Human Services (“HHS”), imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party

reimbursement for our product candidate or a decision by a third-party payor to not cover our product candidate could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, was enacted in March 2010 and continues to significantly impact the health care industry. There have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Ac (the "OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.
The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, or TrumpRx, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again ("MAHA") Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In France, for example, effective access to the market can be achieved either at a free price, decided by the pharmaceutical company, or with a system of cover/reimbursement with a price regulated by the authorities. In this case, the future products must be included, for coverage by hospitals, on the list of proprietary medicinal products approved for use by local authorities and various public services (known as the "*Liste Collectivités*") (Article L. 5123-2 of the Public Health Code) or included on the list of proprietary medicinal products reimbursable to insured persons (known as the "*Liste Sécurité Sociale*") for reimbursement by the Social Security system (Article L. 162-17 of the Social Security Code).

In addition, EU Member States often require the completion of additional health technology assessments that compare the cost- effectiveness of a particular product candidate to currently available therapies. This Health Technology Assessment (HTA) process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. At the EU level, on January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment (HTA Regulation), entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The Regulation establishes a framework for EU-level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

In light of the fact that the United Kingdom has left the EU, Regulation No 2021/2282 on HTA will not apply in the United Kingdom. However, the UK Medicines and Healthcare products Regulation Agency (MHRA) is working with UK HTA bodies and other national organizations, such as the Scottish Medicines Consortium (SMC), the National Institute for Health and Care Excellence (NICE), and the All-Wales Medicines Strategy Group, to introduce new pathways supporting innovative approaches to the safe, timely and efficient development of medicinal products, including, effective as of 31 March 2025, relaunching the Innovative Licensing and Access Pathway with more predicable timelines and closer involvement of the National Health Service.

Indeed, in France, the manufacturer's price excluding tax of medicines reimbursable to insured persons (registered on the Social Security List) is the subject of a multi-year agreement negotiated between each pharmaceutical company and the Economic Committee for Health Products ("CEPS") (failing this, by unilateral decision of the CEPS). A framework agreement has been concluded between Les Enterprises du Médicament ("LEEM"), the trade union representing the pharmaceutical industries, and CEPS. The last framework agreement was signed on March 5, 2021 and has a three-year term. In addition, the transfer prices of medicines on the Sus List and the Retrocession List are also set by agreement between the operating laboratory and the CEPS.

There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

Our business operations in the United States and our arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients may expose us to broadly applicable federal, state, and foreign fraud and abuse and other healthcare laws. These laws may impact, among other things, our research, proposed sales, marketing and education programs of our product candidates that obtain regulatory approval. The healthcare laws and regulations that may affect our ability to operate include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. The intent standard under the federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, which impose penalties and provide for civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and information regarding certain ownership and investment interests held by physicians or their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH” and its implementing regulations, which imposes certain requirements on covered entities and their business associates, and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information; and
- state, local and foreign law equivalents of each of the above federal laws, such as state and foreign anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or registration by pharmaceutical sales representatives; state and foreign laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of EU Member States, national sunshine rules and regulations, industry self-regulation codes of conduct and physicians’ codes of professional conduct. Failure to comply with these requirements could result in administrative penalties, fines or imprisonment, reputational risk and public reprimands.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant administrative, civil, and/or criminal sanctions, including individual imprisonment and exclusion from government funded healthcare programs.

Data Privacy and Security

We are subject to stringent and evolving United States and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security, including the EU’s General Data Protection Regulation ((EU) 2016/679) (“EU GDPR”) and the UK’s General Data Protection Regulation (“UK GDPR”) (collectively, “GDPR”). New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened. Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the CCPA applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages.

The collection and use of personal health data in the EEA is governed by the GDPR, which became effective on May 25, 2018. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EU or the monitoring of the behavior of data subjects in the EU. The GDPR enhances data protection obligations for controllers and processors of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for high-risk processing, limitations on retention of personal data and mandatory data breach notification and privacy by design requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, such as the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim compensation for damages resulting from infringement of the GDPR.

Employees and Human Capital Resources

As of December 31, 2025, we had 125 full-time employees, including approximately 38 with M.D. or Ph.D. degrees, and one part-time employee. Most of these employees are engaged in research and development, clinical development and operations, medical affairs, and biostatistics activities. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of equity-based compensation awards.

Corporate Information

Our legal and commercial name is DBV Technologies S.A. We were incorporated as a *société par actions simplifiée* (S.A.S.) under the laws of the French Republic on March 29, 2002 for a period of 99 years and subsequently converted on March 13, 2003 into a *société anonyme*. We are registered at the Nanterre Commerce and Companies Register under the number 441 772 522. Our principal executive offices are located at 107 Av. de la République, 92320 Châtillon, France, and our telephone number is +33 1 55 42 78 78. Our agent for service of process in the United States is Cogency Global Inc.

Available Information

Our website address is http://www.dbv-technologies.com. We make available on our website, free of charge, our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("the Exchange Act") as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("the SEC"). The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov. Information contained on or accessible through our website is not a part of our Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. The following information about these risks, together with the other information appearing elsewhere in this Annual Report on form 10-K, including our consolidated financial statements and related notes thereto and management's discussion and analysis of financial condition and results of operation, should be carefully considered before a decision to invest in our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. Additional risks that are currently unknown to us or that we currently believe to be immaterial may also impair our business. In these circumstances, the market price of our securities could decline, and holders of our securities may lose all or part of their investment. We cannot provide assurance that any of the events discussed below will not occur.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company, and we have not yet generated significant income from operating activities. We have incurred net losses in each year since our inception in 2002, including net losses of $146.9 million and $113.9 million for the years ended December 31, 2025 and 2024 respectively. As of December 31, 2025, we had an accumulated deficit of $1,553 million. We have devoted most of our financial resources to research and development, including our clinical and pre-clinical development activities. To date, we have financed our operations primarily through the sale of equity securities, obtaining public assistance in support of innovation, reimbursements of research tax credit claims and strategic collaborations. The amount of our future net losses will depend, in part, on the pace and amount of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or additional grants or tax credits. To date, we have not generated any product revenue and we continue to advance the clinical and regulatory development of Viaskin Peanut in the United States and EU. Even if we obtain regulatory approval to market Viaskin Peanut or any other product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for any approved products in those markets. If the prevalence of peanut allergy is lower than we expect or declines, our revenue prospects will be smaller.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of Viaskin Peanut. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek regulatory approvals and pursue commercial activities for Viaskin Peanut, and for which we continue to seek regulatory approvals in the United States;
- continue our research, pre-clinical and clinical development of our product candidates, including additional trials related to our pursuit of regulatory approval of Viaskin Peanut in the United States;
- seek regulatory approvals for our other product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize Viaskin Peanut, if approved, and any other products for which we may obtain regulatory approval, especially in North America;
- further develop the manufacturing process for our product candidates, including any modifications to our patch technology;
- change or add additional manufacturers or suppliers;
- expand the scope of our current clinical trials for our product candidates;
- initiate and conduct any post-approval clinical trials, if required by the FDA or comparable foreign regulatory authorities, for our approved products, if any;
- initiate additional pre-clinical, clinical or other studies for our other product candidates;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain new and existing skilled personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts, as well as a company listed on both the U.S. and French stock markets; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular period or periods, our operating results could be below the expectations of securities analysts or investors, which could cause the price of our ADSs or ordinary shares to decline.

We will require substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.

We are currently advancing our product candidates through pre-clinical and clinical development. Developing product candidates is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we seek regulatory approval for Viaskin Peanut. Furthermore, if we obtain regulatory approval for Viaskin Peanut or any other product candidate that we may develop, we expect our commercialization expenses related to product sales, marketing, distribution and manufacturing to increase significantly as we develop the appropriate infrastructure to commercialize. In addition, our expenses could increase beyond expectations if the FDA requires us to perform nonclinical studies, clinical trials or post-approval clinical trials for our approved products, if any, in addition to those that we currently anticipate.

As of December 31, 2025, our cash and cash equivalents were $194.2 million and we received from the subsequent exercise of the ABSA and BS warrants, a total gross proceed of $94 million (€81 million). Since our inception, we have primarily funded our operations with equity financings, and, to a lesser extent, public assistance aimed at supporting innovation and payments associated with research tax credits (*crédit d'impôt recherche*). We do not generate product revenue and continue to prepare for the potential launch of our first product in the United States and in the European Union, if approved.

We may need to raise additional capital as we prepare for the launch of Viaskin Peanut, if approved, and continue other research and development efforts. We may seek to finance our future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings.

We cannot guarantee that we will be able to obtain the necessary financing to meet our needs or to obtain funds at attractive terms and conditions, including as a result of disruptions to the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to us, including reduced ability to raise additional capital when needed or on acceptable terms, if at all.

If we cannot conduct necessary operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs or ordinary shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The occurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain sufficient funding on a timely basis, we may be required to scale back our operating plan, significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We are limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations.

Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

In addition, the French Commercial Code imposes certain limitations on our ability to price any offering of our share capital without preferential subscription right (*sans droit préférentiel de souscription*), which limitation may prevent us from successfully completing any such offering. Specifically, under the French Commercial Code, unless the offering is less than 10% of issued share capital, securities cannot be sold in an offering at a price that is more than a 10% discount to the volume weighted average trading price on Euronext Paris over the last three trading days preceding the commencement of the marketing of the transaction. In addition, the combined shareholders' meeting dated June 11, 2025 granted authority to our board of directors to increase our share capital up to 100% of issued share capital, if the investors in such offering fit within categories of persons meeting certain characteristics. In this case, securities cannot be sold in such an offering at a price that is more than a 15% discount to (i) the last closing price of the Company's shares on the regulated market Euronext Paris prior to the date on which the issue price is set, (ii) the volume-weighted average price of the share of the Company on the regulated market of Euronext Paris over a period determined by the Board of Directors of between one to five consecutive trading days chosen from the last thirty trading days prior to the date on which the issue price is set.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures. The U.S. Government, including the FDA, has also experienced recent challenges in personnel staffing , which personnel shortages could adversely impact the review and responsiveness on INDs or BLAs.

Future pandemics, epidemics or other public health crises (collectively, "public health crises") could have an impact on our ability to conduct clinical trials, and clinical site initiation, subject enrollment and subject visits (including food challenges) in any of our clinical trials may be suspended or

delayed due to prioritization of hospital resources toward responding to such public health crises. Some participants may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers may adversely impact our future clinical trial operations. Any future public health crises could affect, the broader economies and financial markets, triggering an economic downturn, which at points adversely affected or could adversely affect, our ability to access capital, which could negatively affect our business. In addition, the recession or resulting adverse impacts on the capital markets resulting from any future public health crises, could materially affect our business.

The U.S. Federal Reserve has in recent years raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Our business could be materially and adversely affected by the effects of future public health crises in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. Any future public health crises could materially affect our operations as well as cause significant disruption in the operations and business of third-party manufacturers, CROs, other services providers, and collaborators with whom we conduct business.

It is impossible to predict all effects and the ultimate impact of public health crises. The full extent of the impact of any future public health crises on our clinical development and other operations and financial performance depends on continuing developments that are uncertain and unpredictable, including the timing of any future vaccine development and rollouts and herd immunity, virus mutations and variants, and any new information that may emerge concerning future virus, vaccines, and containment, all of which may vary across regions. Any of these factors could have a material adverse impact on our business, financial condition, operating results, and ability to execute and capitalize on our strategies.

Conflicts could disrupt our and our collaborators' supply chains and adversely affect our and our collaborators' ability to conduct ongoing and future clinical trials of our product candidates. The extent and duration of the military action, sanctions and resulting economic, market and other disruptions are impossible to predict, but could be substantial. Any such disruptions may magnify the impact of the other risks described in this report.

We are obligated to develop and maintain a system of effective internal controls over financial reporting. These internal controls may be determined to be not effective, which may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares and ADSs.

We have been and are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on an annual basis. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective and would be required to disclose any material weaknesses identified in Management's Report on Internal Control over Financial Reporting. While we have established certain procedures and controls over our financial reporting processes, we cannot assure you that these efforts will prevent restatements of our financial statements in the future.

Depending on our future filer status with the SEC, our independent registered public accounting firm may also be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting. For future reporting periods, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective if and when a report from such accounting firm is required, investors could lose confidence in the accuracy and completeness of our financial reports, which could cause the price of our ordinary shares and ADSs to decline, and we could be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Failure to remediate any material weakness in our internal control over financial reporting, or to maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If we do not obtain the capital necessary to fund our operations, we will be unable to successfully commercialize, develop or pursue regulatory approval for our biopharmaceutical products.

The development of biopharmaceutical products is capital-intensive. We anticipate that we will require additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the scope, progress in, results and the costs of, our pre-clinical studies and clinical trials and other research and development programs, particularly as we seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- the approval of Viaskin Peanut by the FDA, European Commission, or other comparable regulatory authorities;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval, especially in North America;
- the costs of securing manufacturing arrangements for commercial production;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements, and any additional collaboration agreements we may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under our existing collaboration agreements and future collaboration agreements, if any; and

- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings. Uncertainty and dislocations in the financial markets have generally made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our future fundraising needs. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding, if obtained, may significantly dilute existing shareholders if that financing is obtained through issuing equity or instruments convertible into equity. We could also be required to seek funds through collaborations or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

The requirements of being a U.S. public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a U.S. public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly as we qualify as a domestic filer. The Exchange Act requires that, we file annual, quarterly and current reports with respect to our business, financial condition and results of operations. We are required to file proxy statements in connection with any meetings of our shareholders. As a result of being a U.S. public company and the accompanying additional reporting requirements, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Compliance with Section 404 may require that we incur substantial accounting expenses and expend significant management efforts. Our independent registered public accounting firm may also be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting.

Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective, the market price of our ordinary shares and ADSs could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC or other applicable regulatory authorities and our business could be harmed.

As a result of disclosure of information in filings required of a U.S. public company, our business and financial condition are more visible than they would be if we were a privately-owned company or if our securities were listed only on Euronext Paris, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and results of operations.

Further, being both a U.S. public company and a French public company has an impact on disclosure of information and compliance with two sets of applicable rules. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Risks Related to Product Development, Regulatory Approval and Commercialization

We depend almost entirely on the successful development of our novel Viaskin technology. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Viaskin products.

We currently have no drug or biological product approved for sale and may never be able to develop a marketable drug or biological product. We may not be successful in developing and commercializing Viaskin Peanut and our other product candidates, including, without limitation, Viaskin Milk, and our commercial opportunities may be limited.

We are currently conducting the OLE phase of VITESSE, a Phase 3 pivotal study in children aged 4 through 7 years of age. Additionally, we are conducting the COMFORT Toddlers supplemental safety study in peanut allergic children 1 through 3 years of age using the Type IV Viaskin Peanut Epicutaneous System (the planned commercial Viaskin Peanut system in this age group, or cVP). In connection with the Accelerated Approval pathway for Viaskin Peanut in toddlers 1-3-years-old we will need to complete a post-marketing confirmatory study to assess the effectiveness of the intended commercial Viaskin Peanut patch that will need to be initiated at the time that the BLA is submitted. Positive results in the studies will be imperative for us to seek regulatory approval before we are permitted to commence commercialization, if ever. The confirmatory study must also be positive post-approval or the FDA may seek withdrawal of approval of Viaskin Peanut in the 1 - 3-year-old age group. Viaskin Milk will also require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence its commercialization, if ever. Our other product candidates are still in pre-clinical or early proof-of-concept phase development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that, among other things, the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing requirements and surveillance, including the completion of pediatric clinical trials to satisfy both U.S. and EU requirements, which will require the expenditure of substantial resources. Of the large number of drugs in development in the United States, only a small percentage successfully completes the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be approved by relevant regulators or will be successfully developed or commercialized.

In addition, in some jurisdictions such as the EU, initiating Phase 3 clinical trials, including clinical trials in the pediatric population, is subject to a requirement to obtain approval from the competent authorities of the EU Member States. For trials involving pediatric populations, sponsors must also have agreed on a Pediatric Investigation Plan (“PIP”) or a granted waiver/deferral. If we do not obtain such approval our ability to conduct clinical trials and obtain marketing authorizations may be severely impaired and our business may be adversely impacted.

We are not permitted to market any of our product candidates in the United States or in any other country until we receive the requisite approval from the applicable regulators. Obtaining requisite regulatory approval in any country is a complex, lengthy, expensive and uncertain process, and the FDA or the applicable foreign regulatory authority may delay, limit or deny approval of a Viaskin product, for many reasons, including, among others:

- we may not be able to demonstrate that a product candidate is a safe and effective treatment, to the satisfaction of the FDA or the applicable foreign regulatory authority;
- the results of our clinical trials or the clinical trials conducted by third party academic institutions and included in our application package may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory authority for regulatory approval;
- the FDA or the applicable foreign regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or the applicable foreign regulatory authority may require that we conduct additional clinical trials;
- the FDA or the applicable foreign regulatory authority may not approve the formulation, labeling or specifications of a product candidate;
- the CROs that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA or the applicable foreign regulatory authority may find the data from pre-clinical studies and clinical trials from a product candidate insufficient to demonstrate that the clinical or other benefits of such product candidate outweighs its respective safety risks;
- the FDA or the applicable foreign regulatory authority may disagree with our analysis or interpretation of data from our pre-clinical studies and clinical trials;
- the FDA or the applicable foreign regulatory authority may not accept data generated at our clinical trial sites;
- an advisory committee, or similar body, may recommend against approval of our application or may recommend that the FDA or the applicable foreign regulatory authority require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA or the applicable foreign regulatory authority may require development or implementation of a REMS or comparable foreign requirements, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory authority may restrict the use of our products to a narrow population;
- the FDA or the applicable foreign regulatory authority may not approve the manufacturing processes or facilities of our own or of third-party manufacturers with which we contract, or may issue inspectional findings that require significant expense and time to address; or
- the FDA or the applicable foreign regulatory authority may change their approval policies or new legislation governing the approval processes.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any of our product candidates based on our Viaskin technology platform. Moreover, because our business is almost entirely dependent upon our Viaskin technology, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Our product candidates have undergone and/or will be required to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulatory authorities, we, or our collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

Pre-clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre-clinical testing and clinical development necessary to commercialize a drug or biologic, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after positive results in earlier trials, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support regulatory approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business and financial condition and on the value of our ADSs and ordinary shares.

In connection with clinical testing and trials, we face a number of risks, including, but not limited to:

- a product candidate is ineffective, inferior to existing approved medicines or treatment options, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested, especially during the double-blind, placebo-controlled food challenges;
- extension studies on long-term tolerance could invalidate the use of our product, showing Viaskin does not generate a sustained protective effect;
- any positive results of earlier testing or trials may not be confirmed by results of subsequent trials; and
- the results may not meet the level of statistical significance required by the FDA or other comparable regulatory authorities to establish the safety and efficacy of our product candidates.

The results of pre-clinical studies do not necessarily predict clinical success, and larger and later-stage clinical trials may not produce the same results as earlier-stage clinical trials. As a result, we may not observe a similarly favorable safety and efficacy profile as our prior clinical trials. For example, in August 2020, we received a CRL in which the FDA indicated it could not approve the Viaskin Peanut BLA in its then-current form. The FDA identified concerns regarding the impact of system adhesion on efficacy and indicated the need for modifications, and new human factors studies. The FDA also indicated that supplementary clinical data would need to be generated to support applications for the Type IV Viaskin Peanut System , or cVP, and requested additional CMC data. Further, in September 2022, we announced that FDA had imposed a partial clinical hold on the VITESSE trial, which was lifted in December 2022 after we made additional revisions to the protocol in order to address FDA concerns. In addition, we cannot assure you that in the course of potential widespread use in future, some drawbacks would not appear in maintaining production quality, protein stability or allergenic strength. Frequently, product candidates developed by pharmaceutical, biopharmaceutical and biotechnology companies have shown positive results in early pre-clinical studies or clinical trials, but have subsequently suffered significant setbacks or failed in later clinical trials. In addition, clinical trials of potential products sometimes reveal that it is not possible or practical to continue development efforts for these product candidates.

If we do not successfully complete pre-clinical and clinical development, we will be unable to market and sell our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an application for regulatory approval may be submitted to the FDA or a comparable foreign regulatory authority. Although there are a large number of drugs and biologics in development in the United States and other countries, only a small percentage result in the submission of an application for regulatory approval to a regulatory authority, such as an NDA or a BLA to the FDA, or comparable foreign regulatory authorities, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed.

In many of our clinical trials, we utilize an oral food challenge procedure intentionally designed to trigger an allergic reaction, which could be severe or life-threatening.

In accordance with our food allergy clinical trial protocols, we utilize a double-blind, placebo-controlled food challenge procedure at various points in our clinical trials. This consists of giving the offending food protein to subjects to assess the sensitivity of their food allergy to determine eligibility to participate and to evaluate the efficacy of our product candidates versus placebo. The food challenge protocol is meant to induce objective symptoms of an allergic reaction. These oral food challenge procedures can potentially trigger anaphylaxis or potentially life-threatening systemic allergic reactions. Even though these procedures are well-controlled, standardized and performed in highly specialized centers with intensive care units, there are inherent risks in conducting a trial of this nature. An uncontrolled allergic reaction could potentially lead to serious or even fatal reactions. Any such serious clinical event could potentially adversely affect our clinical development timelines, including a complete clinical hold on our food allergy clinical trials. We may also become liable to subjects who participate in our clinical trials and experience any such serious or fatal reactions. Any of the foregoing could have a material adverse effect on our business, prospects, stock price or financial condition.

Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay or prevent our ability to generate revenues.

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. The completion of trials for Viaskin Peanut and our other product candidates may be delayed for a variety of reasons, including, but not limited to, delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;

- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;
- obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials;
- manufacturing sufficient quantities of a product candidate;
- obtaining timely responses from and permission to proceed from the FDA under an IND application, or foreign equivalent approval from regulatory authorities outside the United States;
- obtaining IRB approval or positive Ethics Committee opinions as part of the single decision on the authorization of a clinical trial issued by EU Member States including input from the national competent authority and Ethics Committee, to conduct a clinical trial at a prospective clinical trial site;
- determining dosing and clinical design and making related adjustments; and
- subject enrollment, which is a function of many factors, including the size of the population, the nature of the protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

The commencement and completion of clinical trials for our product candidates may be delayed, suspended or terminated due to a number of factors, including:

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation;
- serious adverse events relating to the double-blind, placebo-controlled food challenge procedure when testing participants for the sensitivity of their allergies;
- inability to provide clinical supplies or product candidate necessary for the conduct of clinical trials due to shortages or unavailability;
- delays in lab testing of product candidates required for release for use in clinical trials;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- governmental or regulatory delays, changes by regulatory agencies, including, without limitation, unexpected changes, unrelated to new developments of the science, in prior guidance and instruction provided to us, changes in regulatory requirements, policy and guidelines, and mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;
- delays in enrollment, variability in the number and types of subjects available for clinical trials, and lower-than anticipated retention rates for subjects in clinical trials;
- difficulty in subject monitoring and data collection due to failure of subjects to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as the COVID-19 pandemic or any other pandemics, epidemics, or global health crises, terrorist activities or war, or a natural disaster; and
- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory authorities.

For example, we announced in September 2022 that FDA had imposed a partial clinical hold on the VITESSE trial, which was lifted in December 2022, resulting in a delay in initiation and conduct of the VITESSE trial.

Many of these factors may also ultimately lead to denial of our applications for regulatory approval for our product candidates. If we experience delay, suspensions or terminations of a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed or such revenues could be reduced or fail to materialize.

In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, resource constraints or changes in resources at the regulatory agencies tasked with reviewing our submissions, resulting in delays in receiving timely and consistent guidance, or changes in FDA or other similar foreign regulatory authority policy or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn, varied or suspended. Delays or failures in obtaining regulatory approvals may result in:

- varying interpretations of data and commitments by the FDA and similar foreign regulatory authorities; and
- diminishment of any competitive advantages that such product candidates may have or attain.

Furthermore, if we fail to comply with applicable FDA and other regulatory requirements at any stage during this regulatory process, we may encounter or be subject to:

- issuance of warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- diminishment of any competitive advantages that such product candidates may have or attain;
- suspension, delays or termination in clinical trials or commercialization;
- delays or refusal by the FDA or similar foreign regulatory authorities to review pending applications for regulatory approval or supplements to approved applications;
- voluntary or mandatory product recalls or seizures;
- refusal to permit the import or export of medicinal products or intermediary chemicals;

- suspension, restrictions or additional requirements on operations, including of manufacturing or revocation of necessary licenses;
- withdrawals, variations or suspensions of regulatory approvals; and
- fines, civil penalties, and criminal prosecutions.

If our product candidates are not approved by the FDA, or comparable foreign regulatory authorities, we will be unable to commercialize them in the United States or in other countries.

The FDA must approve any new drug or biologic before it can be commercialized, marketed, promoted or sold in the United States. We must provide the FDA with data from pre-clinical studies and clinical trials that demonstrate that, among other things, our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. There is significant competition to secure clinical trial support resources, including CROs. Clinical sites are resource constrained with the availability of these sites further limited due to, in certain instances, participation in multiple clinical trials. In addition, there are various opportunities for subjects eligible to participate in our clinical trials to participate in other food allergy clinical trials or allergy related trials. We must provide data to ensure the identity, strength, quality and purity of the drug substance and drug product. Also, we must assure the FDA that the characteristics and performance of the clinical batches will be replicated consistently in the commercial batches. We will not obtain approval for a product candidate unless and until the FDA approves a BLA, if at all.

The processes by which regulatory approvals are obtained from the FDA to market and sell a new or repositioned product are complex, require a number of years and involve the expenditure of substantial resources. We have already experienced several setbacks and delays in our previously anticipated ability to obtain approval of Viaskin Peanut from the FDA and the European Commission, and we may experience additional delays in the future. We cannot assure you that any of our product candidates will receive FDA approval, or regulatory approval from a comparable foreign regulatory authority, in the future, and the time for receipt of any such approval is currently incapable of estimation.

A Fast Track designation by the FDA, or equivalent foreign programs, may not actually lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive regulatory approval.

We have obtained Fast Track designation from the FDA for the development of Viaskin Peanut and Viaskin Milk, and we may apply for that designation for other product candidates as well. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation. The FDA has broad discretion to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do have Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Generally, a Fast Track designation affords the possibility of rolling review, enabling the FDA to review portions of our marketing application before submission of a complete application. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

The regulatory approval process outside the United States varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our product candidates in the European Union and many other jurisdictions, we, and our collaborators, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing.

We may, in the future, conduct clinical trials for, and seek regulatory approval to market, product candidates in countries other than the United States. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the United States, or we may simultaneously seek regulatory approvals in the United States and other countries. If we or our collaborators seek marketing approvals for a product candidate outside the United States, we will be subject to the regulatory requirements of health authorities in each country in which we seek approvals. With respect to marketing authorizations in the European Union, we will be required to submit an MAA to the EMA or the national competent authorities of EU Member States, which conduct a validation and scientific review process in evaluating a product for safety and efficacy. The regulatory approval procedures vary among countries and may involve additional testing, and the time required to obtain approvals may differ from that required to obtain FDA approval.

Pursuing regulatory approvals from regulatory authorities in countries outside the United States is likely to subject us to all of the risks associated with pursuing FDA approval described above. In addition, regulatory approval by the FDA does not ensure approval by the regulatory authorities of any other country, and approval by foreign regulatory authorities does not ensure regulatory approval by the FDA.

Even if we, or our collaborators, obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or they market our products, which could materially impair our ability to generate revenue.

Even if we receive regulatory approval for Viaskin Peanut or any of our other product candidates, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or limit the patient population that may utilize the product or require a product to carry a warning in its labeling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive regulatory approval for Viaskin Peanut or any of our other product candidates, we and our collaborators will continue to expend time, money and effort in all areas of regulatory compliance.

Any of our product candidates for which we, or our collaborators, obtain regulatory approval in the future could be subject to post-marketing requirements, post-marketing commitments or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our product candidates for which we, or our collaborators, obtain regulatory approval in the future, as well as the manufacturing processes, post-marketing requirements and commitments, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval will be subject to limitations on the indicated uses for which the product may be marketed or may be subject to other conditions of approval, including, without limitation, FDA requirement that we pre-clear all promotional materials with the agency and the FDA requirement to implement a REMS, or comparable foreign requirements to ensure that the benefits of a drug or biological product outweigh its risks.

The FDA or comparable foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long-term observational studies on natural exposure. The FDA and other agencies, including, without limitation, the U.S. Department of Justice, and comparable foreign regulatory authorities closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, market any of our product candidates for which we, or they, receive regulatory approval for treatment other than their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed.

We sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory, and other product development objectives or milestones for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of regulatory approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- our ability to pursue Accelerated Approval or any other actionable regulatory pathway for our product candidates;
- our receipt of approvals, if any, by the FDA and other comparable foreign regulatory authorities and the timing thereof;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing, as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, the trading price of the ADSs or ordinary shares may decline.

Access to raw materials and products necessary for the conduct of clinical trials, for commercialization, if approved, and manufacturing of our product candidates and product, if any, is not guaranteed.

We are dependent on third parties for the supply of various materials, chemical or biological products that are necessary to produce Viaskin patches for our clinical trials, and will need to depend on third parties to produce patches for our commercial supply, if Viaskin Peanut is approved. The supply of these materials could be reduced or interrupted at any time, including, without limitation, as a result of impacts due to pandemics, epidemics or other global health crises, natural disasters, new laws or regulations applicable to us or our suppliers, or other unfavorable global economic conditions, including as a result of the ongoing conflict between Russia-Ukraine, Israel-Hamas and other global political or military conflicts. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If key suppliers or manufacturers are lost or the supply of materials is diminished or discontinued, we may not be able to continue to develop, manufacture and market our product candidates or products, if any, in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing.

Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products, if any, in a cost-effective and timely manner. To prevent such situations, we intend to diversify our supply sources by identifying a second source of supply for critical raw materials and materials, such as natural protein. If we encounter difficulties in the supply of these materials, chemicals or biological products, if we were not able to maintain our supply agreements or establish new agreements to develop and manufacture our products in the future, our business, prospects, financial condition, results and development could be significantly affected.

Relying on third-party manufacturers may result in delays in our clinical development or commercialization efforts.

Developing and commercializing new medicines entails significant risks and expenses. Our clinical trials may be delayed if third-party manufacturers are unable to assure a sufficient quantity of the drug product to meet our study needs. Currently, we have only one manufacturer, Sanofi S.A., or Sanofi, of the API used in our Viaskin product candidates, including Viaskin Peanut, such as peanut protein extract and unmodified allergen milk extract. In February 2020, Sanofi announced that it planned to create a new company dedicated to the production and marketing to third parties of API. Subsequently, Sanofi consolidated its API commercial and development activities conducted in six of its European API production sites. While those API sites do not include the site in which the API used in our Viaskin product candidates is produced, there can be no assurances that this transition will not adversely impact our supply of API from Sanofi. If Sanofi does not continue to manufacture the API as required by us in a timely manner, we may not be able to find a substitute manufacturer on a timely basis and our commercialization efforts and clinical trials may be delayed. Notwithstanding contractual protections, Sanofi may be able to utilize knowledge gained through their relationship with us in furtherance of their development of competitive therapies.

In December 2025, Stallergenes Greer announced that it intends to discontinue the commercialization of Palforzia, on July 31, 2026, for business reasons.

We also expect to rely on Sanofi and on FAREVA for the manufacturing of the patch and on other third-party manufacturers for the manufacturing of commercial supply of Viaskin Peanut, if approved, and any other product for which we obtain regulatory approval. Sanofi may not be able to effectively scale its manufacturing capacity of our API to meet our commercialization needs and we may be unable to establish any agreements with other third-party manufacturers or to do so on acceptable terms. Even if Sanofi is able to meet our commercialization needs or if we are able to establish agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of products with which we contract are required to operate in accordance with FDA-mandated cGMPs or comparable GMP requirements in foreign countries. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch or availability of products based on our product candidates into the market. Moreover, the constituent parts of a combination product retain their regulatory status (as a biologic or medical device, for example) and, as such, we or our contract manufacturers may be subject to additional requirements in the QSR or comparable quality management systems in foreign countries, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third-party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Failure by third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including shutdown of the third-party vendor, fines, injunctions, civil penalties, revocation or suspension of regulatory approval for any products granted pre-market approvals, invalidation of drug product lots or processes, seizures or recalls of products, operating restrictions, and criminal prosecutions.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products, if approved, may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

Our Viaskin product candidates may not be able to be manufactured profitably on a large enough scale to support commercialization.

To date, our Viaskin product candidates have only been manufactured at a scale which is adequate to supply our research activities and clinical trials. There can be no assurance that the procedures currently used to manufacture our product candidates will work at a scale which is adequate for commercial needs and we may encounter difficulties in the production of Viaskin patches due to our or our partners' manufacturing capabilities. For example, in large-scale use, there is a possibility that our electrospray manufacturing tool, ES GEN4.0, may have issues related to maintenance of production quality, protein stability, and allergenicity. Additionally, during production, the containment of the electrospray function and the use of the allergen in liquid form keep the environment from being contaminated by the allergens. However, if there is a malfunction in the handling or storage phases or during the production phases, allergens could be released into the atmosphere and sensitize anyone present in the environment. We have not built commercial-scale manufacturing facilities, and we have limited manufacturing experience with Viaskin patches.

Additionally, while the production process was developed in strict compliance with current regulations, due to the originality of the product, we cannot predict if European or U.S. regulatory authorities will make new regulations applicable to our production process, or if we will have any future disagreements with such regulatory authorities regarding our interpretation of the regulatory requirements.

We rely on a single supplier to produce, or contract for the production of, active ingredients and we rely on a single manufacturer to produce patches for our clinical trials and for our commercial supplies of any future approved products. Even if we were to obtain access to quantities of active ingredients sufficient to allow us otherwise to expand our Viaskin manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all. In the event our Viaskin product candidates cannot be manufactured in sufficient quantities for commercialization, our future prospects could be significantly impacted and our financial prospects would be materially harmed.

We, or the third parties upon whom we depend, may be adversely affected by earthquakes, other natural disasters or outbreaks of contagious diseases and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes, other natural disasters or an outbreak of a contagious disease could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities or infrastructure, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

We rely, and will rely in the future, on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.

We rely, and will rely in the future, on medical institutions, clinical investigators, CROs, contract laboratories and collaborators to perform data collection and analysis and others to carry out our clinical trials. Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

Even if collaborators with which we contract in the future successfully complete clinical trials of our product candidates, those candidates may not be commercialized successfully for other reasons.

Even if we contract with collaborators that successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including

- failing to receive regulatory approval to market them as drugs;
- being subject to proprietary rights held by others;
- failing to obtain approval from regulatory authorities on the manufacturing of our products;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable;
- failing to compete effectively with products or treatments commercialized by competitors; or
- failing to show long-term risk/benefit ratio of our products.

Currently, we do not have commercial-ready marketing and sales infrastructure. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

We currently have a limited commercial infrastructure. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. For example, we are planning to hire sales representatives for the marketing of Viaskin Peanut in the United States, if approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, hire, retain and incentivize adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with establishing an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services for the commercialization of Viaskin Peanut in the United States or the European Union, if approved, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market Viaskin Peanut or any of our other product candidates or may be unable to do so when needed or on terms that are favorable to us. We likely will have more limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively, or they may fail to comply with promotional requirements for prescription products that could render our products misbranded in violation of government regulations and thus potentially subject to enforcement. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Viaskin Peanut or any of our other product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing Viaskin Peanut or any of our other product candidates, either on our own or through collaborations with one or more third parties, our business, results of operations, financial condition and prospects will be materially and adversely affected.

Our product candidates are regulated as biological products, or biologics, which may subject them to competition sooner than anticipated.

The BPCIA established an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. “Biosimilarity” means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. To meet the higher standard of “interchangeability,” an applicant must provide sufficient information to show biosimilarity and demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administrated more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Under the BPCIA, an application for a biosimilar or interchangeable product cannot be approved by the FDA until 12 years after the reference product was first licensed, and the FDA will not even accept an application for review until four years after the date of first licensure. The law is evolving, complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty and could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for biosimilar or interchangeable competition sooner than anticipated.

In the EU, following grant of a related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product. After this period, an application for marketing authorization for a generic or biosimilar product may be submitted, and the innovator’s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years following authorization of the reference product, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is, however, no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of a related application for MA. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

Even if any of our product candidates are commercialized, they may not be accepted by physicians, patients, or the medical community in general. Even if we, or our collaborators, are able to commercialize our product candidates, the products may become subject to market conditions that could harm our business.

Even if the medical community accepts a product as safe and efficacious for its indicated use, prescribers may choose to restrict the use of the product if we are, or any collaborator is, unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives regulatory approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator’s ability to educate the medical community about the safety and effectiveness of the product;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the product;
- the market price of our product relative to competing treatments; and
- our ability to effectively implement a scientific publication strategy.

We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us.

The biopharmaceuticals industry is highly competitive. Numerous biopharmaceutical and biotechnology companies, universities and other research entities are actively involved in the discovery, development and commercialization of therapeutic options to treat allergies, making it a highly competitive field. We have competitors in several jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Although we believe we are currently in a unique position with respect to the testing and treatment of food allergies in children, established competitors may invest heavily to quickly discover and develop novel compounds that could make any of our product candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to any of our product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

In the case of food allergies, we are aware of several food allergy academic studies and pharmaceutical developmental efforts connected with such studies that are currently being conducted in major medical centers and hospitals worldwide. These studies are evaluating forms of allergen desensitization treatments such as OIT, SLIT, SCIT, OMIT, CIT and INT immunotherapy, or products using synthetic allergens, denatured allergens, small molecule inhibitors, or combinations of medicines or methods, or medicines using traditional methods such as Chinese herbs.

Studies combining other methods of allergen immunotherapy, such as OIT, with monoclonal antibodies (anti-IgE and anti-IL-4Rα) as adjunct therapy are being conducted currently. These types of co-administrations may significantly improve the safety of specific allergen immunotherapies administered orally or subcutaneously. Monoclonal antibodies, used alone as monotherapy or in combination with allergen immunotherapy, may become significant competitors to our products. In February 2024, the FDA approved Xolair® (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

There is one treatment that is specific for peanut allergy in children 1 to 17 years of age, a proprietary form of OIT which was approved by the FDA and the European Commission: Palforzia, formulation of peanut flour developed by Aimmune. Nestlé S.A. acquired Aimmune in October 2020, and divested the Palforzia business to Stallergenes Greer in September 2023. In December 2025, Stallergenes Greer announced that it will discontinue commercialization of Palforzia on July 31, 2026.

Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues if we obtain regulatory approval to market a product.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may adversely affect one or more of the following:

- our ability or our collaborators' ability to set a price we believe is fair for our products, if approved;
- our ability or our collaborators' ability to obtain and maintain market acceptance by the medical community and patients;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Third-party payors are increasingly reducing reimbursements for medical products, drugs and services. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Limited third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

Various provisions of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, were designed to impact the provision of, or payment for, health care in the United States. There have been amendments to and executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, or TrumpRx, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on

imported pharmaceutical products; and (4) as part of the Make America Healthy Again (“MAHA”) Commission’s Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers’ global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court’s Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for a medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment (“HTA”) of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. On January 12, 2025, Regulation No. 2021/2282 on Health Technology Assessment, amending Directive 2011/24/EU entered into force on January 12, 2025 through a phased implementation. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and establishes the framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices. We believe that pricing pressures at the federal and state levels in the United States, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators.

Guidelines and recommendations published by various organizations may impact the use or reimbursement of Viaskin Peanut, if approved.

Government authorities promulgate regulations and guidelines that may be directly applicable to us and any approved products. However, professional societies, practice management groups, insurance carriers, physicians’ groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payors, as well as patient communities.

Recommendations by government authorities or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review (“ICER”) which publish their findings and offer recommendations relating to the products’ reimbursement by government and private payors. In July 2019, ICER published its final report assessing the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin Peanut and a competitor product candidate. The results of this or any future ICER report or any similar recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use or reimbursement of Viaskin Peanut, if approved, could have a material adverse effect on our results of operations and financial condition. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of Viaskin Peanut, if approved, could adversely affect the market price of our securities.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if any.

Our product candidates are being developed to address the needs of allergic patients, for some of whom they can have a profound and life-threatening adverse reaction if exposed to even minute amounts of an allergen. Accordingly, safety is of paramount importance in developing these product candidates. To date, more than twelve clinical trials of Viaskin Peanut and Viaskin Milk product candidates have been conducted both outside and inside of the United States in over 2,000 human subjects to evaluate the safety and efficacy of these product candidates for the treatment of peanut allergies and milk allergies, respectively. Adverse events observed in these clinical trials have primarily involved general disorders such skin and subcutaneous tissue, immune system and administration site conditions, such as erythema, pruritus, edema and urticaria. However, in clinical trials to date, one case of mild to moderate anaphylaxis has been reported, and it is possible that anaphylaxis or other systemic reactions may occur in the future. It is worth noting that, as a desensitization patch bringing the allergen into contact with the skin, reactions, which are a source of itching and discomfort for subjects, are common. This reaction is typically temporary in duration and fades after a few weeks of use. In addition, during daily administration of the patches during treatments, depending on the severity of the allergies and subject response to treatment, precautionary measures are necessary when handling the patches after use due to risk of contamination.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, halt or terminate clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Further, if our Viaskin patch product candidates receive regulatory approval and we or others identify undesirable side effects caused by the products (or any other similar products) after approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the products;
- regulatory authorities may require the addition of labeling statements, such as a “boxed” warning or a contraindication;
- we may be required to change the way the products are distributed or administered, conduct additional clinical trials or change the labeling of the products;
- we may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected products and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize product candidates based on our Viaskin technology platform in multiple markets, including but not limited to those within the United States and Europe. If we commercialize product candidates based on our Viaskin technology platform in foreign markets, we would be subject to additional risks and uncertainties, including:

- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations;
- patients’ ability to obtain reimbursement for Viaskin patch products in foreign markets; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of Viaskin patch products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, integrity obligations, exclusion from government healthcare programs, individual imprisonment, contractual damages, reputational harm and diminished profits and future earnings, among other consequences.

Healthcare providers and others will play a primary role in the recommendation and prescription of Viaskin patch products, if approved. Our arrangements with such persons and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute Viaskin patch products, if we obtain regulatory approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include but are not limited to the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, order or recommendation of any item, good, facility or service for which payment may be made

under federal healthcare programs such as Medicare and Medicaid. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. The intent standard under the federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

- The federal civil and criminal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government.
- HIPAA, which created federal criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- HIPAA, as amended by HITECH, and its implementing regulations, which impose certain requirements on covered entities and their business associates, and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.
- Analogous state, local or foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require certain regulatory licenses to manufacture or distribute our products commercially and/or registration of pharmaceutical sales representatives; state and foreign laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our current and/or future business activities could be subject to challenge under one or more of these laws. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could substantially disrupt our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

Changes in regulatory requirements, or guidance from the FDA or comparable foreign regulatory authorities or unanticipated events during our clinical trials of Viaskin products may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

Changes in regulatory requirements, or guidance from the FDA or comparable foreign regulatory authorities or unanticipated events during our clinical trials may force us to amend clinical trial protocols or the FDA or certain foreign regulatory authorities may impose additional clinical trial requirements. Discussions with regulatory authorities have caused us to adjust certain trial protocols. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs or competent foreign regulatory authorities, for review and approval, as applicable, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for the Viaskin patch product candidates, or any other product candidates, may be harmed and our ability to generate product revenue will be delayed.

In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission and other comparable regulatory authorities responsible for clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved.

The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized application system, coordinated review procedures, expanded reporting and increased transparency obligations. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, required financial, technical and human resources

Moreover, following a public consultation that began in 2022, the United Kingdom government has enacted new legislation to overhaul the clinical trials regulatory framework. In April 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, remove unnecessary administrative burdens on trial sponsors, and protect the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials into closer alignment with the CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period. While these changes introduce efficiencies and align with some principles of the CTR, divergence between the United Kingdom and EU regulatory systems remains. Any significant divergence could affect the cost and complexity of conducting clinical trials in the United Kingdom and may impact the acceptability of United Kingdom-based trial data for seeking marketing authorizations in the EU, and vice versa.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the "Pharma Package"). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package - comprised of a new directive and regulation to replace existing legislation – aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions; reshape the incentives regime for orphan medicinal products; and expand the Bolar exemption. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

The FDA and other comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other comparable foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as Viaskin patch products, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other comparable foreign regulatory authorities, as reflected in the product's approved labeling. If we receive regulatory approval for Viaskin patch products as a treatment for a particular allergy, physicians, in their independent professional medical judgment, may nevertheless prescribe Viaskin patch products to their patients in a manner that is inconsistent with the approved label. Additionally, it is permissible to share in certain circumstances and in accordance with applicable FDA, and comparable regulatory authorities', guidance and regulations truthful and non-misleading information that is consistent with, but not contained in, the product's approved labeling. If we are found to have promoted off-label uses or promoted our product before approval, we may become subject to significant liability under the FDCA and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA and other U.S. government agencies has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the marketing of Viaskin patch products, if approved, by restricting off-label promotion, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Similar limitations and penalties are provided in the EU both at EU level and at national level in individual EU Member States.

Our product development programs may require substantial financial resources and may ultimately be unsuccessful.

The success of our business depends primarily upon our ability to identify, develop and commercialize products to treat food allergies. In addition to Viaskin Peanut, we may pursue development of our other development programs, including Viaskin Milk. None of our other product candidates and potential product candidates has commenced any clinical trials since we scaled down our research and clinical development efforts in 2020 and 2021 to focus on Viaskin Peanut. There are a number of FDA or foreign requirements that we must satisfy before we can commence clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. We may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or comparable foreign regulatory authorities. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not secure collaborations with strategic partners to test, commercialize and manufacture certain product candidates outside of food allergies, we may not be able to successfully develop products and generate meaningful revenues.

A key aspect of our current strategy is to selectively enter into collaborations with third parties to conduct clinical testing. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We currently have multiple collaboration agreements in effect, including collaborations for the development of applications in the field of respiratory allergies or autoimmune disease, as well as other therapeutic domains, such as vaccines. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize products using our product candidates. Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid, is not infringed by potential competitors or is unenforceable or the product candidate infringes on the intellectual property rights of others;

- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

Managing Growth and Transitioning to the Commercial Phase.

In December 2025, DBV reported positive preliminary results from the Phase 3 VITESSE study of the Viaskin Peanut patch in children aged 4 to 7 with peanut allergies, reinforcing the preparation for the next regulatory steps. DBV has thus entered an acceleration phase characterized by (i) the continued advanced clinical development of Viaskin® Peanut, (ii) the preparation of the BLA in the United States, and (iii) the establishment of pre-commercial and commercial capabilities, subject to regulatory approvals. This transition entails a substantial increase in operational capacity (quality, regulatory affairs, clinical operations, supply chain, manufacturing in a regulated environment, market access, pharmacovigilance, and medical information) and a scaling up of human, financial, and information system resources. A poorly managed ramp-up could lead to delays, cost overruns, regulatory non-compliance, a deterioration in quality metrics, and failures in the coordination of service providers and suppliers.

The transition from an R&D-focused model to one that incorporates pre-marketing and, where applicable, the marketing of Viaskin® Peanut requires, in particular:

• ongoing compliance of internal control systems and manufacturing processes with local and federal requirements;

• securing and ensuring redundancy in the supply chain (raw materials, components, production sites);

• the ability to forecast demand, plan batches, and manage distribution;

• the activation of market access, medical affairs, and pharmacovigilance functions, as well as the management of post-marketing safety data, where applicable.

Any shortfall in any of these areas could delay or jeopardize the achievement of regulatory/commercial milestones, significantly increase costs, and damage DBV's reputation.

Furthermore, the Company is not currently generating revenue and has historically recorded significant operating losses. The commercialization phase of the VIASKIN Peanut patch for children aged 4 to 7 in the United States remains contingent upon access to additional financing, which may not be available in a timely manner, on acceptable terms, or may result in substantial dilution of existing shareholders.

The materialization of all or part of the above risks could: (i) delay submissions or prolong regulatory reviews, (ii) delay the industrial ramp-up, (iii) increase expenses beyond forecasts, (iv) reduce financial flexibility, and, generally, have a material adverse effect on DBV's business, financial condition, results, and prospects.

Intellectual Property Risks Related to Our Business

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates for the treatment of common food or other allergies, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, and their uses from unauthorized use by third parties, to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain and/or maintain patent protection for our product candidates is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we may not have been the first to file patent applications for our product candidates or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not protect, encompass, or embody commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents;
- our issued patents could potentially be found to be unenforceable; or
- others may identify prior art or other bases which could invalidate our patents.

Even if we have or obtain patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to our compositions or products. There are many issued U.S. and foreign patents relating to

biological or chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the allergy treatment field in which we are developing products. Any or all of these could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue as patents, and because there can be procedures to keep some applications secret, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process and after a patent grants. There may also be significant expenses associated with enforcing and/or defending various patents in a patent portfolio or with challenging patents that could unfairly exclude our products and product candidates from being marketed once approved. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction (perhaps irrevocably). If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Legal actions to enforce and/or defend our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents and/or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations. If we develop a reputation of failing to attempt to protect or to enforce our intellectual property rights, our competitive position could suffer, which could harm results of operation.

Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the USPTO are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference or derivation proceedings; U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO (collectively, "post-grant proceedings"). Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, derivation, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection of our product candidates, we could lose our competitive advantage and competition we face could increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court, the United States Court of Appeals for the Federal Circuit, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business. For example, recently the federal courts and the United States Supreme Court have issued (and may issue additional) rulings generally related to standards for upholding the validity of biological and chemical "genus" claims. Any rulings that make it more difficult to uphold the validity of biological or chemical "genus" claims could potentially negatively impact our patent portfolio and negatively impact our business.

In addition, the Leahy-Smith America Invents Act (the "America Invents Act") which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed and prosecuted during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed (and continues to develop) new and untested, or relatively lightly tested, regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is still not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

In addition, over the past few years, bills in the U.S. Congress have been proposed that, if passed, would make changes to the America Invents Act. For example, bills have been introduced that would reduce the discretion of the Patent Trial and Appeal Board ("PTAB") to deny some or all post-grant proceedings. In addition, bills, rules and/or regulations have been introduced that would and do provide the director of the USPTO more authority to set aside PTAB decisions. Further, at least one other bill has been introduced that would essentially revert the patent system to the pre-America Invents Act patent system. If these bills are eventually passed by the U.S. Congress and become law, they could impact our ability to enforce/defend patents.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We do, and expect to, enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting, defending, and maintaining patents, and defending other intellectual property rights such as trade secrets, on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are generally based on the priority dates of each of our patent applications.

Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing in these or other jurisdictions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties under certain circumstances. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country or jurisdiction-by-jurisdiction basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we may have to negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's materials, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents or other intellectual property rights, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect

our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us.

Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations.

If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and the price of the ADSs. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- us or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business and financial condition. As a result, we could be prevented from commercializing current or future product candidates.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The biopharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing Viaskin patch products.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity or enforceability of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our product candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all; and
- in the case of trademark claims, redesign, or rename, Viaskin or other trademarks we may own, to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations of lack of candor or good faith in dealing with USPTO, that someone connected with prosecution of the patent withheld relevant and/or material information from the USPTO, or made a false statement, during prosecution. Third parties may also raise similar claims regarding invalidity and/or unenforceability before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review, and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover, encompass, or protect our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. If a party were to prevail on a legal assertion of unenforceability, such a holding could also affect other related patents. Such a loss of patent protection would have a material adverse impact on our business.

Risks Related to Our Organization, Structure and Operations

We depend on key personnel and attracting qualified management personnel and our business could be harmed if we lose key personnel and cannot attract new personnel.

Our success depends to a significant degree upon the technical and management skills of our officers and key personnel. The loss of the services of any of these individuals would likely have an adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified

management. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our key executives could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain marketing approval of and commercialize products.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to: comply with the regulations of the FDA and applicable foreign regulatory authorities, provide accurate information to the FDA and applicable foreign regulatory authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical products. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient’s condition, injury or even death. For example, product liability claims may be brought by subjects participating in our clinical trials as a result of unexpected side effects from our product candidates. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, other biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we may be forced to limit or forgo further commercialization of the affected products.

We may incur significant costs from class action litigation.

The market price for our ordinary shares or ADSs recently has and may continue to fluctuate for many reasons, including as a result of public announcements regarding the progress of our development and commercialization efforts or the development and commercialization efforts of our collaborators and/or competitors, the addition or departure of our key personnel, variations in our operating results and changes in market valuations of pharmaceutical and biotechnology companies. When the market price of a security has been volatile as the market price for our ordinary shares and ADSs has been, holders of that security have occasionally brought securities class action litigation against the company that issued the security.

For example, in December 2018, we announced that we voluntarily withdrew our BLA for Viaskin Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls, and our ADS price declined significantly as a result. Following this announcement, a class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey alleging that we and our former Chief Executive Officer, our current Chief Executive Officer, our former Deputy Chief Executive Officer, and our former Chief Business Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The plaintiffs sought unspecified damages on behalf of a purported class of persons that purchased our securities between February 14, 2018 and August 4, 2020 and also held our securities on December 20, 2018 and/or March 16, 2020 and/or August 4, 2020. The complaint, as amended, was dismissed with prejudice on July 29, 2022, and the matter was resolved with finality thirty days thereafter.

Whether or not a plaintiff’s claims are successful, this type of litigation is often expensive and diverts management’s attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management’s attention and resources, which could cause serious harm to our business, operating results and financial condition. We maintain liability insurance; however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial condition and operations.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. We currently carry product liability insurance coverage for our clinical trials.

Although we maintain such insurance, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims by us or our partners, licensees or subcontractors, which could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully.

Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our Operating Income

We may be subject to tax reviews and audits relating to (i) the determination and allocation of the tax loss (including its carryforward status and the proper documentation of its constituent elements) and (ii) the transfer pricing policy applied within the Company (methodology, comparables, value chain, allocation of functions/assets/risks, and consistency with contractual cash flows). These audits may be conducted retrospectively and cover several fiscal years. The tax authorities assess the Company's practices in compliance with the tax rules in force in the relevant jurisdictions and with generally accepted arm's length principles. The Company has a tax loss in France of approximately $1.5 billion and $3 million in the United States as of December 31, 2025.

As a French technology company, we have benefited from certain tax advantages, including, for example, the French Research Tax Credit (*crédit d'impôt recherche*) ("CIR"). The CIR is a French tax credit aimed at stimulating research and development. Beginning in the fiscal year ending December 31, 2021, the Company recovered its Small and Medium-sized Enterprises, or SMEs, status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented $5.6 million and $4.2 million, as of December 31, 2025 and 2024 respectively. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR tax benefit or could not grant Tax agreement to our Contract Research Organizations. The French tax authorities may challenge our eligibility to, or our calculation of certain tax reductions and/or deductions in respect of our research and development activities and, should the French tax authorities be successful, we may be liable to additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the French Parliament decides to eliminate, or reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

We may be exposed to significant foreign exchange risk. Exchange rate fluctuations may adversely affect the foreign currency value of our ADSs.

We are exposed to increasing foreign exchange risk due to a portion of our supplies sourced in the United States and invoiced in U.S. dollars, as well as the operations of our subsidiary DBV Technologies Inc., given our preparations for the potential launch of the VIASKIN Peanut patch in the United States, should it receive FDA approval. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. This exposure is exacerbated by the high level of volatility of the U.S. dollar over the past year, which increases uncertainty regarding foreign exchange transaction costs.

The ADSs are quoted in U.S. dollars on the Nasdaq Capital Market and our ordinary shares are trading in euros on Euronext Paris. Our financial statements are prepared in U.S. dollars. Fluctuations in the exchange rate between euros and the U.S. dollar will affect, among other matters, the U.S. dollar value and the euro value of our ordinary shares and ADSs.

Climate change, extreme weather events, and evolving sustainability regulations could disrupt our third-party CRO/CMO and supplier operations, increase costs, and delay our development and manufacturing timelines.

The increased frequency of extreme weather events (fires, floods, storms, heat waves) could disrupt the operations of the CROs and CMOs that we use. Such disruptions could delay the manufacturing of clinical batches, the delivery of research devices, or the conduct of clinical trials, impacting execution timelines.

Transition risks include the implementation of stricter emissions or sustainability regulations, which could increase costs or lead times for suppliers and industrial partners. These developments could indirectly affect the availability and cost of services necessary for the development of DBV's product candidates.

The Company is not subject to the CSRD reporting obligations or the CS3D (CSDDD) due diligence obligations at this stage, given the reduced scope and postponement of application phases decided at the European level under the Omnibus Directive and the "Stop-the-Clock" mechanism (a two-year delay for phases 2 and 3; refocusing on companies with more than 1,000 employees and more than €450 million in revenue). The Group maintains formal regulatory monitoring (EU/France) to incorporate expected clarifications on the Omnibus Directive and the revised ESRS, and to adapt its practices should its status change. In the United States, regulatory bodies do not yet provide for sustainability obligations for issuers at this stage.

We may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. For example, in production, the confinement of the electrospray function and the use of the allergen in liquid form make it possible to prevent the allergens from contaminating the environment. However, we cannot assure you that in case of malfunction during the handling, storage or production process, allergen would not be released into the atmosphere and sensitize the persons present in the environment. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state, local or foreign laws and

regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. An allegation of noncompliance by applicable regulatory authorities with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, , numerous states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These states allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 ("CCPA"_ applies to personal data of consumers, business representatives, and employees who are California residents, and imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, these developments may increase compliance costs and potential liability with respect to other personal data we maintain about California residents.In addition, similar laws are being considered in several other states, as well as at the federal, state, and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing personal data. For example, under the GDPR, government regulators may impose temporary or definitive bans on data processing and other corrective actions, fines of up to €20 million under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue , whichever is greater. Furthermore, companies may face private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the European Economic Area, or EEA, or in other foreign jurisdictions). Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, , such as the European standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. Other countries outside Europe (e.g., Russia, China, Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business.

If we cannot transfer personal data from one jurisdiction to another, for example, from the EEA, the UK or other jurisdictions to the United States in a lawful manner, or if the requirements for such lawful transfers of personal data are too onerous, we may face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions, the inability to transfer data and collaborate with partners, vendors, and other third parties. Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, employment of certain individuals and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials, and other statements, concerning data privacy, and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations including, providing appropriate notice to data subjects, obtaining necessary consents, or establishing a legal basis for the transfer and processing of the data by us, could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we or the third parties with whom we work fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; payment of damages; bans or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; revision or restructuring of our operations; or loss of revenue or profits; and other adverse business consequences.

If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, may process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

Cyberattacks, malicious internet-based activity, and online and offline fraud threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. These threats are prevalent and continue to increase. These threats come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists", organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties with whom we work may be subject to a variety of evolving threats, including, but not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, flood, attacks enhanced or facilitated by artificial intelligence, and other similar threats.

Severe ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks. Supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Additionally, our workforce's use of network connections, computers, and devices outside our premises or networks, including working remotely from home, while in transit, and in public locations, poses increased risks to our information technology systems and data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not previously identified while conducting due diligence acquired or integrated entities and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to sensitive information held by us or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption disrupt our ability (and that of third parties with whom we work) to conduct our business operations.

We may expend significant resources or modify our business activities to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry-standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of the third parties with whom we work). We have not and may not be able to detect and remediate all such vulnerabilities including on a timely basis because threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversions of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant material consequences may cause interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

At this stage, our strategy does not involve plans to acquire companies or technologies facilitating or enabling us to access to new medicines, new research projects or new geographical areas, or enabling us to express synergies with our existing operations. However, if our strategy changes or if such acquisitions were to become necessary in the future, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions under favorable conditions, and could be led to finance these acquisitions using cash that could be allocated to other purposes in the context of existing operations. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction, which could have a material adverse effect on our business, financial conditions, earnings and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

International trade policies, including tariffs, sanctions, and trade barriers may adversely affect our business, financial condition, results of operations, and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for Viaskin, Viaskin Peanut and other product candidates. We currently rely, and expect to continue to rely, on third parties for the manufacture of Viaskin epicutaneous patch, Viaskin Peanut and other product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States, and the principal suppliers of many of our critical raw materials are located in Europe. The API for Viaskin Peanut is manufactured in France. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our

development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward potential commercialization of Viaskin Peanut, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn or escalation in trade tensions could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects.

We will need to develop and implement sales, marketing and distribution capabilities before we are able to bring any product candidate to market, and as a result, we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of December 31, 2025, we had 125 full-time employees. Before we can commercialize Viaskin Peanut, if approved, and any of our other product candidates in North America, we will need to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing any such development activities we may pursue. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Risks Related to Ownership of Our Ordinary Shares and ADSs

The market price for our ordinary shares and ADSs may be volatile or may decline regardless of our operating performance.

The trading price of our ADSs and ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of our securities depends on a number of factors, including those described in this “Risk Factors” section, many of which are beyond our control and may not be related to our operating performance.

Our ADSs were sold in our initial public offering on Nasdaq in October 2014 at a closing price of $21.64 per share, and the closing price per ADS has ranged from as low as $3.25 and as high as $22.76 during 2025 (with the current ratio of five (5) ordinary shares to one (1) ADS). During this same period, our ordinary share prices have ranged from as low as €0.645 to as high as €3.68. The market price of our securities may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- regulatory actions with respect to our products or our competitors’ products, including the potential resubmission to the FDA of a BLA for Viaskin Peanut;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs and/or ordinary shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes in the structure of healthcare payment systems;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions. These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and

biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Share ownership is concentrated in the hands of our principal shareholders and management, who will continue to be able to exercise a direct or indirect controlling influence on us.

As of December 31, 2025, our executive officers, directors, current 5% or greater shareholders and affiliated entities, including entities affiliated with Baker Bros. Advisors LP, entities affiliated with Suvretta Capital Management., entities affiliated with Artisan Partners, L.P., entities affiliated with Invus, entities affiliated with Adage Capital Management L.P., entities affiliated with MPM Capital and entities affiliated with Bpifrance, together beneficially own approximately 49% of our ordinary shares. As a result, these shareholders, acting together, will have significant influence over all matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate action might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and trading volume could decline.

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our ADSs or ordinary shares or publishes incorrect or unfavorable research about our business, the price of our ADSs and ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our ADSs or ordinary shares, demand for our ADSs and ordinary shares could decrease, which could cause the price of our ADSs or ordinary shares or trading volume to decline.

If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, our ADSs could be delisted.

Our ADSs are currently listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy certain continued listing requirements and standards, including, among others, minimum stockholders' equity, minimum share price, director independence and independent committee requirements, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards.

For instance, on December 20, 2023, we received a letter from the Listing Qualifications Staff of Nasdaq notifying the us that for the last 30 consecutive business days, the bid price of our ADSs had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2). On May 31, 2024, the Company announced plans to change the ratio of its ADS to its ordinary shares (the "ADS Ratio"), nominal value €0.10 (ten cents) per share, from the current ADS Ratio of one (1) ADS to one-half (1/2) of one (1) ordinary share to a new ADS Ratio of one (1) ADS to one (1) ordinary share (the "ADS Ratio Change"). The ADS Ratio Change was effective on June 7, 2024. In addition, to obtain an additional 180 days period to regain compliance with the NASDAQ minimum bid price requirement, the Company applied to transfer its securities from the NASDAQ Global Select Market to the NASDAQ Capital Market (the "NCM"). On June 18, 2024, the Company was notified by the Listing Qualifications Department that NASDAQ granted the Company's request to transfer the listing of its ADSs from the NASDAQ Global Select Market tier to the NCM tier, and that NASDAQ granted the Company's request for a second 180-day period, or until December 16, 2024, to regain compliance with the $1.00 bid price requirement. The Company's ADSs were transferred to the NCM at the opening of business on June 20, 2024. On November 11, 2024, the Company announced plans to implement an additional ADS ratio change from the ratio of one (1) ADS to one (1) ordinary share to a ratio of one (1) ADS to five (5) ordinary shares. This ratio change was effect on November 29, 2024. On December 13, 2024, the Company received notice from Nasdaq confirming that the Company regained compliance with the minimum closing bid price criteria of the Nasdaq listing requirements.

Notwithstanding our ability to regain compliance with the Nasdaq Listing Rules, we may fail to satisfy one or more Nasdaq requirements for continued listing of our ADSs in the future. In the event that our ADSs are delisted from Nasdaq and are not eligible for quotation or listing on another market or exchange, trading of our ADSs could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our ADSs, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our ADSs to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Delisting would also likely have a negative effect on the price of our ADSs, would affect our ability to raise additional capital through the public or private sale of equity securities, and would impair your ability to sell or purchase our ADSs when you wish to do so. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional interest and fewer business development opportunities. In the event of a delisting, we may take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our ADSs to become listed again, stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from dropping below Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment, if any, will depend on appreciation in the price of the ADSs. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth.

Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs. Investors seeking cash dividends should not purchase the ADSs. Further, under

French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our annual financial statements. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

In addition, exchange rate fluctuations may affect the amount of euros that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

Future sales of ordinary shares or ADSs by existing shareholders could depress their market price

We cannot predict whether future issuances or the availability of ordinary shares or ADSs for resale in the open market will decrease their market price. We are not restricted from issuing additional securities including any securities that are convertible into or exchangeable for, or that represent the right to receive ordinary shares or ADSs. Sales of a substantial number of ordinary shares or ADSs in the public market or the perception that such sales might occur could materially adversely affect their market price. Because our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings. Thus, our stockholders bear the risk of any future stock issuances reducing the market price of our ordinary shares or ADSs and diluting their stock holdings in us. The exercise of the warrants detailed within *Item 7. Forward looking*, the exercise of any warrants granted to directors, executive officers and other employees under our stock compensation plans, the issuance of ordinary shares or ADSs in acquisitions and other issuances of ordinary shares or ADSs could have an adverse effect on their market price, and the existence of warrants may materially adversely affect the terms upon which we may be able to obtain additional capital in the future through the sale of equity securities.

The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of the ADSs.

Our ADSs are traded on the Nasdaq Capital Market, and our ordinary shares are listed on Euronext Paris. The dual listing of our ordinary shares and our ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the maintenance of an active trading market for our ADSs in the United States. The price of our ADSs could also be adversely affected by trading in our ordinary shares on Euronext Paris, and vice versa. In addition, currency fluctuations as between the euro and U.S. dollar may have an adverse impact on the value of our ADSs.

Our by-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our by-laws and the corporate laws of France, the country in which we are incorporated, could make it more difficult for a third-party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our by-laws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, a non-French resident as well as any French entity controlled by non-French residents may have to file a declaration for statistical purposes with the Banque de France, within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- under French law, certain investments in a French company relating to certain strategic industries by individuals or entities not established in a Member State of the EU are subject to prior authorization of the Ministry of Economy;
- the owner of 90% of the share capital and voting rights of a public company listed on a regulated market in an EEA country, including from the main French Stock Exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors' broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can only be convened by our chairman or our managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions; however, this mode of participation (by way of videoconference or teleconference) does not apply to the adoption of decisions taken for the closing of the accounts for the fiscal year, including the consolidated financial statements;
- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;

- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our by-laws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations;
- transfers of shares shall comply with applicable insider trading rules and regulations and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of the by-laws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by at least a two thirds majority vote of our shareholders present, represented by a proxy or voting by mail at the meeting.

You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

You may instruct the depositary of your ADSs to vote the ordinary shares underlying your ADSs. If the depositary timely receives voting instructions from you, it will endeavor to vote the securities (in person or by proxy) represented by the ADSs in accordance with such voting instructions. If the depositary receives voting instructions which fail to specify the manner in which the depositary is to vote the deposited securities, you will be deemed to have instructed the depositary to vote in favor of all resolutions endorsed by our board of directors. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the ordinary shares underlying the ADSs you hold. However, you may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for your instructions, the depositary, upon timely notice from us, will notify you of the upcoming vote and arrange to deliver our voting materials to you. We cannot guarantee you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares or to withdraw your ordinary shares so that you can vote them yourself. If the depositary does not receive timely voting instructions from you, it may give a proxy to a person designated by us to vote the ordinary shares underlying your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote, and there may be nothing you can do if the ordinary shares underlying your ADSs are not voted as you requested.

Your right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings.

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis, transferable during a period starting two days prior to the opening of the subscription period or, if that day is not a trading day, the preceding trading day; and ending two days prior to the closing of the subscription period or, of that day is not a trading day, the preceding trading day, unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, the ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying ordinary shares.

Your ADSs, which may be evidenced by ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

The biotechnology industry has been included in the list of critical technologies subject to foreign investment control procedure in France, which may limit the ability to certain non-French investors to any offering of our securities.

The completion of any investment (i) by (a) an individual of foreign nationality, (b) any individual of French nationality not domiciled in France within the meaning of article 4B of the French General Tax Code (*Code général des impôts*), (c) any entity governed by foreign law, and (d) any entity governed by French law controlled by one or more of the entities referred to in (a) to (c), (ii) which would result in (a) the acquisition of control—within the meaning of article L. 233-3 of the French Commercial Code (*Code de commerce*)—of a French company, (b) the acquisition of all or part of a branch of activity of a French company, or (c) for individuals who are not nationals of a Member State of the European Union or of a State party to the agreement on the European Economic Area that has entered into an administrative assistance agreement with France and/or are not domiciled in one of these States, or for legal entities of which at least one of the members of the control chain is not governed by the law of one of these States or is not a national and/or is not domiciled there, to cross the threshold of 25% of the voting rights of a French company, or (d) for individuals who are not nationals of a Member State of the EU or of a State party to the agreement on the EEA that has entered into an administrative assistance agreement with France and/or are not domiciled in one of these State, or for legal entities of which at least one of the members of the control chain is not governed by the law of one of these States or is not a national and/or is not domiciled there, to cross the threshold of 10% of the voting rights of a French company whose shares are admitted to trading on a regulated market and (iii) whose activities concern, even occasionally, the research and development of so-called critical technologies, such as biotechnologies, and considered essential to the protection of public health, is subject to prior authorization by the French Minister of the Economy *(ministère de l'Économie*). The French Decree No. 2023-1293 of December 28, 2023 has made permanent the temporary regime under French Decree No. 2022-1622 of December 23, 2022, which expired on December 31, 2023.

The crossing of the threshold of 10% of the voting rights of French companies whose shares are admitted to trading on a regulated market is subject to a fast track review procedure (filing of a simplified form, delay for the Minister to respond limited to 10 days, transaction deemed authorized in the absence of a response at the end of the delay).

If an investment in the Company requiring the prior authorization of the Minister of the Economy is made without such authorization having been granted, the Minister of the Economy may cancel the transaction or order (possibly under financial penalty) the investor concerned (i) to submit an application for authorization, (ii) to have the previous situation restored at its own expense or (iii) to modify the investment. In addition, the Minister may impose undertakings and conditions on the investor (including regular reporting commitments). The investor concerned could also be declared criminally liable and be sanctioned, in particular, by exclusion from any public contract or by a fine which may not exceed the highest of the following three amounts: (i) twice the amount of the investment concerned, (ii) 10% of the Company's annual pre-tax revenues and (iii) €5 million (for a company) or €1 million (for an individual). The application of these regulations is likely to constitute a potential barrier to investments made by investors located outside the European Economic Area and could therefore limit the Company's access to sources of financing.

U.S. investors may have difficulty enforcing civil liabilities against our company and directors and senior management.

Certain members of our board of directors and senior management, and those of our subsidiaries, are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a French company with limited liability. Our corporate affairs are governed by our by-laws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our board of directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our board of directors is required by French law to consider the interests of our company, our shareholders, employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or are in addition to, your interests as a shareholder.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our ADSs less attractive to investors.

We are currently a "smaller reporting company" as defined in the Exchange Act . We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We will be a smaller reporting company and may take advantage of the scaled disclosures available to smaller reporting companies for so long as (i) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) (a) our annual revenue is less than $100.0 million during the most recently completed fiscal year and (b) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not accelerated smaller reporting companies. These scaled disclosure requirements include, but are not limited to, the following:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding financial information; and
- reduced disclosure obligations regarding executive compensation.

We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our ADSs less attractive if we rely on certain or all of these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ADS price may be more volatile.

U.S. holders may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Under the U.S. Internal Revenue Code of 1986, as amended (the "Code"), we will be a passive foreign investment company, or PFIC, for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets, including cash, consists of assets that produce, or are held for the production of, "passive income." Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains. Whether we will be a PFIC in any year depends on the composition of our income and the nature and composition of our assets, which we expect may vary substantially over time. Based on the composition of our gross income and the nature and composition of our gross assets, we believe that we were not a PFIC for the taxable year ending December 31, 2025. Because the determination of our PFIC status is based on complicated provisions of the Code and applicable administrative authorities, there can be no assurance that our conclusions concerning our PFIC status for the taxable year ending December 31, 2025 are correct and will not be successfully challenged by applicable tax authorities, and we cannot provide any assurance regarding our PFIC status for the current taxable year or any future taxable year.

If you are a shareholder that is a United States person for U.S. federal income tax purposes, or a U.S. holder during a taxable year when the Company is considered a PFIC, then regardless of whether we continue to be characterized as a PFIC in subsequent taxable years, you may suffer adverse tax consequences, including the treatment of gains realized on the sale of our ADSs as ordinary income, rather than as capital gain, the inapplicability of the preferential rate that otherwise would be applicable to dividends received on our ADSs by individual U.S. holders, the addition of interest charges to the tax on such gains and certain distributions, and additional reporting requirements.

A U.S. holder in certain circumstances may mitigate the adverse tax consequences of the PFIC rules by filing an election to treat the PFIC "qualified electing fund" ("QEF") or, if shares of the PFIC are "marketable stock" for purposes of the PFIC rules, by making a mark-to-market election with respect to the shares of the PFIC. For any taxable year in which we are a PFIC, we will determine whether we will provide to U.S. holders the information required to make a QEF election; for the taxable year ending December 31, 2025, we have provided that information. However, there is no assurance that such information will be provided in future taxable years, and prospective investors should not assume that a QEF election will be available.

U.S. Holders are strongly urged to consult with, and rely solely upon, their personal tax advisors regarding the implications of the tax provisions applicable to U.S. persons who own, directly or indirectly, interests in a foreign corporation that is or may become a PFIC.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical infrastructure, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials and technology platform ("Information Systems and Data").

Our Information Systems security function, led by our Vice President for Information Systems and Director of Information Systems security, helps identify, assess and manage the Company's cybersecurity threats and risks. This function evaluates risks by continuously monitoring and analyzing our threat environment and risk profile using various methods including automated tools, subscribing toreports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the Company's threat environment, evaluating threats that are reported to us, conducting internal audits, internal and external threat assessments, third party threat assessments, and conducting vulnerability assessments.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data. These include, for example: an information systems security policy; security incident management; disaster recovery procedures; periodic backup recovery tests; risk assessments; encryption of certain data; network security controls; data segregation for certain systems and environments; access controls; physical security; asset management, tracking, and disposal; systems monitoring; employee training and phishing simulations; periodic penetration tests; outsourced managed detection and response services; maintaining cybersecurity insurance; and having dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, cybersecurity risk is addressed as a component of the Company's enterprise risk management program and identified in the Company's risk mapping and management documentation. The cybersecurity component of the Company's risk mapping and management documentation is updated

annually, and our Information Systems security function prepares cybersecurity roadmaps designed to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example, cybersecurity software providers, managed cybersecurity service providers, and penetration testing firms.

We use third-party service providers to perform a variety of functions throughout our business, such as CROs, CMOs, cloud hosting and other SaaS providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, we take various measures designed to help manage risk associated with our use of certain of these providers. These measures include, for example, obtaining confirmation of certain cybersecurity certifications, information security questionnaires, and imposition of certain contractual obligations.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report, including ***If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.***

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee is responsible for overseeing the Company's cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including, but not limited to, Cyril Guyardeau, our Director of Information Systems Security, who had previously spent 15 years as an IT infrastructure engineer in the healthcare industry, and Cecile Delansorne, our Vice President for Information Systems, who has held similar executive positions overseeing information systems in other pharmaceutical companies for over seven years. Our Vice President for Information Systems reports to our Chief Financial Officer.

The Vice President for Information Systems is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. The Vice President for Information Systems is also responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our Information System security incident management procedure is designed to escalate certain cybersecurity incidents to members of management depending on the impact of the incident, including the Chief Financial Officer, Data Privacy Officer, Company Legal department, and Executive Committee, who work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified.

The audit committee may receive periodic reports from our Chief Financial Officer concerning the Company's significant threats and risk, including, if applicable, those related to cybersecurity threats, and the processes the Company has implemented to address them. The Audit Committee also may have access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters are located in Châtillon, France. Our principal offices occupy a 2,447 square meter facility, pursuant to a lease agreement dated November, 2023, which commenced as of April 16, 2024 with an expiration in March 2033.

Our primary U.S. office is located in Warren, New Jersey. In February 2024, we entered into a sublease agreement, commencing on March 19, 2024 and effective for 70 months, for an office of 16,704 square feet in Warren, New Jersey. We also had a 5,799 square foot office in Basking Ridge, New Jersey to support our U.S. operations, which commenced on April 1, 2022 and expired as of June 1, 2025.

We consider our facilities to be suitable and adequate for the management and operation of our business.

Item 3. Legal Proceedings.

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently subject to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ADSs were transferred from the Nasdaq Global Select Market to the Nasdaq Capital Market on June 18, 2024 under the symbol “DBVT.” Prior to that date, our ADSs were listed on the Nasdaq Global Select Market under the symbol “DBVT” since October 22, 2014. Prior to that date, there was no public trading market for our ADSs.

Our ordinary shares have been trading on Euronext Paris under the symbol “DBV” since March 28, 2012. Prior to that date, there was no public trading market for our ADSs or our ordinary shares.

Holders of Ordinary Shares

As of December 31, 2025, there were approximately 330 holders of record of our ordinary shares and 64 holders of record of our ADSs. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities. The number of beneficial owners of the ADSs in the United States is likely to be much larger than the number of record holders of our ordinary shares in the United States.

Dividend Policy

We have never paid cash dividends on any of our share capital and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved].

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read this discussion and analysis of our financial condition and consolidated results of operations together with the consolidated financial statements, related notes and other financial information included in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including statements of our plans, objectives, expectations and intentions, contain forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section titled “Forward-Looking Statements.”

Overview

We are a late-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin. Our therapeutic approach is based on EPIT, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin, an epicutaneous patch (i.e., a skin patch). We have generated significant data demonstrating that Viaskin’s mechanism of action is novel and differentiated. Viaskin targets specific antigen-presenting immune cells in the skin, called Langerhans cells, that capture the antigen and migrate to the lymph node in order to activate the immune system without passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to treat children suffering from food allergies, for whom safety is paramount, since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as anaphylactic shock. We believe Viaskin may offer convenient, self-administered, non-invasive immunotherapy to patients, if approved.

Our most advanced product candidate is Viaskin Peanut, which has been evaluated as a potential therapy for children with peanut allergy in twelve clinical trials, including three Phase 2 trials and four completed Phase 3 trials. We have two ongoing Phase 3 trial of Viaskin Peanut in children ages one to three and ages four to seven with peanut allergy.

2025 Year in review

In 2025, the Company made significant progress advancing the VIASKIN Peanut patch toward commercialization (if approved), secured transformative financing, and identified regulatory pathways for our product candidates through discussions with and written responses from the FDA. As we enter 2026, our focus shifts toward commercialization and laying the groundwork to transform the lives of children living with peanut allergy.

Since March 2025, we have increased cash and cash equivalents through our financing activities. We believe our cash and cash equivalents, (as of the date of this report as of December 31, 2025), are sufficient to pursue operations and prepare for the potential U.S. launch of the VIASKIN Peanut patch for children aged 4–7, if approved.

The Company has proven our ability to perform under pressure and achieve key results, as seen in the announcement of the positive topline results of the VITESSE clinical study and successful financing. The Company’s goal is to broaden FDA-approved options for pediatric peanut allergy while delivering value to stakeholders.

Financing

March 2025 PIPE Financing

The Company raised proceeds in the 2025 PIPE consisting of i) a share capital increase without preferential subscription rights reserved to categories of persons satisfying determined characteristics pursuant to the 24th resolution of the 2024 General Meeting completed on April 7 2025, for an amount of €38 million ($40 million), consisting of the issuance of (i) 34,090,004 new shares at a par value of €0.10 (the "New Shares") each with warrants of the Company attached (the "ABSA Warrants", and together with the New Shares, the "ABSA") at a subscription price of €1.1136 per ABSA and (ii) up to 59,657,507 additional new shares, if all the ABSA Warrants attached to the New Shares are exercised (the "ABSA Warrant Shares"); and ii) the issue through an offering reserved to categories of persons satisfying determined characteristics of 71,005,656 units (the “PFW-BS-PFW”) completed on April 7, 2025 for an amount of €79 million ($85 million) at a subscription price of €1.1136 per PFW-BS-PFW (of which €1.1036 will have been prefunded on the issue date), each PFW-BS-PFW consisting of one pre-funded warrant to subscribe for one share of the Company (the "First Pre-Funded Warrants") and one warrant (the "BS Warrants") to subscribe to one second pre-funded warrants (the "Second Pre-Funded Warrants"), each of which entitles the holder to subscribe for 1.75 shares of the Company (the "Second PFW Shares"), allowing to issue up to 71,005,656 additional new shares if all the First Pre-Funded Warrants are exercised (the "First PFW Shares") and up to 124,259,898 additional new shares if all the Second Pre-Funded Warrants are exercised (the "Second PFW Shares", together with the ABSA Warrant Shares and the First Pre-Funded Warrant Shares, the "Warrant Shares", and together with the New Shares, the "Offered Shares"). The Company received initial gross proceeds of $125.5 million (€116.3 million) on April 7, 2025.

On January 16, 2026, the Company announced additional gross proceeds of $195 million (€166.7 million at the exchange rate of 1 EUR = $1.17) resulting from the full exercise of the ABSA Warrants and BS Warrants, following the announcement of the positive VITESSE Topline Results on December 16, 2025. Of these proceeds, $100.7 million in gross proceeds (€85.7 million, at the exchange rate of 1 EUR = $1.17) was received as of December 31, 2025, with the remaining amount received in January 2026.

The Accounting treatment is detailed into **Note 1 Nature of the business and principles and accounting methods, Significant contracts**.

At-The-Market (ATM) equity program offering

In September 2025, the Company entered into a Sales Agreement (the "Sales Agreement") with Citizens JMP Securities, LLC ("Citizens"), with respect to an equity offering program (the "ATM Offering") pursuant to which the Company may offer and sell ADSs, from time to time, through Citizens as its sales agent. Pursuant to the Sales Agreement and a prospectus supplement the Company has filed related to the ATM Offering, the Company may offer and sell ADSs having an aggregate offering price of up to $150.0 million from time to time through Citizens. The issuance and sale, if any, of the ADSs by the Company under the Sales Agreement will be made pursuant to the Company's previously filed and effective registration statement on Form S-3 (Registration Statement No. 333-271166). Sales of the Company's ADSs, if any, in the ATM Offering may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act from time to time. Pursuant to the ATM Offering, the Company received (i) a total gross amount of $30 million from the sale of 11,538,460 Ordinary Shares (underlying 2,307,692 ADSs) on October 6, 2025, (ii) a total gross amount of $30 million from the sale of 10,714,300 Ordinary Shares (underlying 2,142,860 ADSs) on October 29, 2025, and (iii) a total gross amount of $5 million from the sale of 1,700,000 Ordinary Shares (underlying 340,000 ADSs) on November 19, 2025.

Our Consolidated Financial Statements have been prepared assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. All assumptions pertaining to this estimate are detailed below in the ***Liquidity and Capital Resources*** discussion**.**

Clinical & Regulatory

On January 8, 2025, the Company announced positive 3-year results from EPITOPE Phase 3 Open-Label Extension Study, a Phase 3 clinical trial. The EPITOPE OLE data demonstrated continued improvement in treatment benefit of VIASKIN® Peanut patch in toddlers 1 – 3 years through 36 months.

On March 24, 2025, the Company secured an agreement with FDA on Safety Exposure Data required for BLA for Viaskin® Peanut Patch in 4 – 7-year-olds, accelerating the timeline for a BLA filing to the first half of 2026.

On June 25, 2025, the Company announced the first subject screened in COMFORT Toddlers Supplemental Safety Study in Peanut Allergic Toddlers 1 – 3 Years Old.

On November 11, 2025, the Company announced the last-patient-last-visit in the VITESSE Phase 3 clinical trial evaluating the VIASKIN® Peanut patch in peanut-allergic children aged 4 to 7 years.

On December 16, 2025, the Company announced positive Topline Results from Phase 3 VITESSE Trial of VIASKIN® Peanut Patch in Peanut Allergic Children Aged 4-7 Years.

- VITESSE met its primary endpoint: the lower bound of the 95% confidence interval the difference between treatment arms was 24.5%, exceeding the prespecified threshold of 15%.
- 46.6% of children treated with the VIASKIN® Peanut patch met response criteria at 12 months, compared to 14.8% of children in the placebo arm.
- Safety results were consistent with the safety profile observed in the VIASKIN Peanut clinical program to date.
- BLA submission in 4-7-year-olds on track for the first half of 2026.
- Achievement of primary endpoint triggers an acceleration of the exercise period of certain warrants issued pursuant to the 2025 PIPE financing

The clinical development history of the program is described into **Item 1 Business: Our Viaskin Technology Platform** of this document.

Partnerships, Research & Developments.

The Company relies on various subcontractors to conduct its operations, the principal categories of which include:

- CROs: These leading international organizations perform, on behalf of the Company, all activities related to regulatory clinical trials once the study protocol has been finalized.
- CMOs: As the Company does not currently hold the regulatory status of a pharmaceutical establishment, these entities manufacture the batches of patches required for preclinical and clinical development on the Company's behalf.

The Company's dedicated partners also supply the proteins necessary for the manufacture of patches'batches, as well as various patch components and other materials required for production.

A summary of these agreements is provided in **Item 1 Business : Manufacturing and Supply** of this document.

Governance

On July 22, 2025, the Company announced the appointment of James Briggs as Chief Human Resources Officer, succeeding Caroline Daniere. James Briggs leads key initiatives supporting DBV's transition from a development-stage biotechnology company to a potential commercial-stage organization.

On September 18, 2025, the Company announced the resignation of Daniel Soland from his position as a member of the Company's Board of Directors, effective immediately.

On October 30, 2025, the Company announced the provisional appointment of a new independent director, Dr. Philina Lee, to its Board of Directors, replacing Daniel Soland, subject to ratification by shareholders at DBV's next annual shareholder meeting. Dr. Lee also serves as a member of the Board's Compensation Committee.

On November 3, 2025, the Company announced the appointment of Kevin Trapp as Chief Commercial Officer, responsible for the global commercial strategy and its execution for the Viaskin Peanut patch.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes the results of our operations, derived from our consolidated financial statements, prepared in compliance with generally accepted accounting principles in the United States, or U.S. GAAP, for the years ended December 31, 2025 and 2024:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
Operating income	**5,636**	**4,151**	**1,485**	**36 %**
Operating expenses				
Research and development expenses	(116,682)	(89,342)	(27,340)	31 %
Sales and marketing expenses	(3,222)	(2,659)	(562)	21 %
General and administrative expenses	(32,788)	(28,739)	(4,049)	14 %
Total Operating expenses	**(152,692)**	**(120,740)**	**(31,952)**	**26 %**
Loss from operations	**(147,056)**	**(116,589)**	**(30,467)**	**26 %**
Financial income (expense)	601	2,726	(2,126)	(78)%
Loss before taxes	**(146,456)**	**(113,863)**	**(32,593)**	**29 %**
Income tax	(491)	(55)	(436)	789 %
Net loss	**(146,947)**	**(113,918)**	**(33,029)**	**29 %**
Basic/diluted Net loss per share attributable to shareholders	**(1.05)**	**(1.17)**	**—**	**—**

Operating Income

The following table summarizes our operating income for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
Research tax credit	5,636	4,146	1,489	36 %
Other operating income	—	5	(5)	
Total Operating income	**5,636**	**4,151**	**1,485**	**36 %**

The Company did not generate Revenue from operating activities in 2025 or 2024.

This caption consists of Research Tax Credit (*crédit d'impôt recherche*, or CIR) that is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific researches. The Company was granted $5.6 million for the year ended December 31, 2025 compared to $4.2 million for the year ended December 31, 2024. The increase is the result of more eligible activities were carried out in the period.

Operating Expenses

Since our inception, our operating expenses have consisted primarily of Research and Development activities, General and Administration costs and to lesser extent sales and marketing costs.

Research and Development Expenses

The following table summarizes our research and development expenses for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
Research and Development expenses				
External clinical-related expenses	67,949	61,060	6,890	11%
Employee-related costs	20,522	17,213	3,309	19%
Pre-Commercial Inventory	16,062	1,388	14,674	1057%
Share-based payment expenses	2,261	2,343	(82)	(4)%
Depreciation, amortization and other costs	9,889	7,338	2,551	35%
Total Research and Development expenses	**116,682**	**89,342**	**27,341**	**31%**

Research and Development expenses increased by $27.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024.

The caption Pre-Commercial Inventory of $16.1 million reflects efforts launched by the company in inventory build-up to support commercial readiness in anticipation of potential FDA approval (written down as they do not meet recognition criteria).

External clinical-related expenses increased by $6.9 million, due to higher clinical trial activity driven by the initiation of patient recruitment for COMFORT Toddlers study. These increases were partially offset by (1) reduced spending on the VITESSE study following completion of final patient visits in 2025 and (2) lower costs from other studies that are completed or nearing completion.

Employee-related costs, excluding share-based payments, increased by $3.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily driven by growth in full-time employees ("FTE"). This increase reflects the full-year impact in 2025 of hires made in 2024, combined with additional recruitments in 2025. These hires were mainly in Medical Affairs, Quality, and Regulatory functions, primarily based in the United States, and were made to support BLA submission and Commercial readiness activities. The increase also includes certain one-off costs related to the strong operational execution delivered in 2025.

Depreciation, amortization and other costs increased by $2.6 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, consequently to an accrual reversal related to CRO activities in the prior year, had a positive impact on the income statement and offsets the recurring depreciation and amortization.

In the year ended December 31, 2025, we spent $116.7 million in Research and Development expenses to advance the development of our product candidates. The following table provides a breakdown of our direct Research and Development expenses for our two lead development programs, as well as expenses not allocated to the programs and share-based compensation expenses included in Research and Development expenses, for the years ended December 31, 2025 and 2024, respectively:

	December 31,	
	2025	**2024**
Viaskin Peanut [1]	107,221	80,479
As a percentage of research and development expenses, excluding share-based compensation Expense	94%	93%
Research and development expenses related to Viaskin Milk [1]	222	3,638
As a percentage of research and development expenses excluding share-based compensation Expense	—%	4%
Other research and development expenses [1]	6,978	2,881
Total research and development expenses, excluding share-based compensation expense	114,421	86,999
Share-based compensation expenses included in research and development expenses	2,261	2,343
Total research and development expenses	116,682	89,343

[1] Excludes employee share-based compensation expense

Sales and Marketing

Sales and marketing expense consists primarily of personnel costs, consultant fees and share-based compensation for sales and marketing employees, as well as fees related to pre-commercialization activities for Viaskin Peanut in North America and in the European Union. We anticipate that our sales and marketing expenses will increase significantly in the future as we prepare for the potential launch and commercialization of Viaskin Peanut in North America and in the European Union, if approved. The following table summarizes our sales and marketing expenses for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
Sales & Marketing expenses				
External professional services and other costs	1,967	1,770	197	11 %
Employee-related costs incl. share-based payment expenses	1,254	890	364	41 %
Total Sales & Marketing expenses	**3,222**	**2,659**	**561**	**21 %**

Sales and marketing expenses increased by $0.6 million for the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was primarily attributable to the expansion of headcount and market research activities to support commercial readiness for Viaskin Peanut in North America.

General and Administrative

The following table summarizes our general and administrative expenses for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
General & Administrative expenses				
External professional services	9,072	10,052	(980)	(10)%
Employee-related costs	12,972	8,981	3,991	44 %
Share-based payment expenses	3,012	2,161	851	39 %
Depreciation, amortization and other costs	7,731	7,545	186	2 %
Total General & Administrative expenses	**32,788**	**28,739**	**4,049**	**14 %**

General and administrative expenses increased by $4.0 million for the year ended December 31, 2025, compared to the year ended December 31, 2024.

The increase was primarily driven by higher employee-related costs (excluding share-based compensation), which rose by $4.0 million as the Company continued to scale its organization in preparation for commercial operations. The growth in full-time employees was concentrated in Human Resources, Information Solutions, Finance, and Legal and Compliance, reflecting targeted investments in the core infrastructure required to achieve commercial readiness for Viaskin Peanut in North America. These additions were designed to strengthen operational capabilities, enhance organizational maturity, and support the transition toward a potential commercial launch, if approved.

The increase also reflects certain one-off costs associated with the strong operational execution delivered in 2025, including preparatory initiatives tied to commercial planning and organizational enablement.

These increases were partially offset by a $(1.0) million decrease in external professional services, primarily due to the absence of prior-year one-time expenses related to office relocations in France and the United States, as well as reduced trademark and patent-related activities.

Finance Income (Expense)

Our cash and cash equivalents have been deposited primarily in savings and deposit accounts with a short term remaining maturity at the date of purchase or less, refundable within 32 days or less, for which the risk of changes in value is considered to be insignificant. Savings and deposit accounts generate a limited amount of interest income, with very low counterparty risks. We expect to continue this investment strategy.

Our financial income was $0.6 million in 2025 and $2.7 million in 2024, and primarily includes the financial income on our financial assets and foreign exchange gains.

Income tax

Our income tax expense was $491 thousand for the year ended December 31, 2025, compared to an income tax expense of $55 thousand for the year ended December 31, 2024.

Net loss

Net loss was $146.9 million for the year ended December 31, 2025, compared to $113.9 million for the year ended December 31, 2024. Net loss per share (based on the weighted average number of shares outstanding over the period) was $1.05 and $1.17 for the year ended December 31, 2025 and 2024, respectively.

Liquidity and Capital Resources

Our financing strategy is to maintain financial flexibility to meet working capital requirements including commercial inventory build and manufacturing capacity expansion to support demand of VIASKIN Peanut patches in the United States and Europe, if approved.

Financial Condition

On December 31, 2025, we held $194.2 million in cash and cash equivalents compared to $32.5 million of cash and cash equivalents on December 31, 2024. Net cash used for operating activities was $121.2 million and $104.5 million for the years ended December 31, 2025 and 2024, respectively. In the year ending December 31, 2025, we recorded a net loss of $146.9 million. Our net cash flows provided by financing activities totaled $276.2 million in 2025 and $0.6 million in 2024, mainly consisting of the proceeds from the 2025 PIPE and sales from our ATM program.

Sources of Liquidity and Material Cash Requirements

Since its inception and up to December 31, 2025, the Company has received a total of approximately $1.6 billion in equity financing, almost all of which relates to cash proceeds from capital increases. The Company obtained the following gross proceeds from various financings through the issuance of securities during the last five years :

In Million dollars	Equity capital	Bank loan	Other debt	Total
2022	209.7	—	—	209.7
2023	7.8	—	—	7.8
2024	—		—	—
2025	291.5			291.5
Total	**509.0**	**—**	**—**	**509.0**

In June 2022, the Company announced an aggregate $194 million private investment in public equity (“PIPE”) financing from the sale of 32,855,669 ordinary shares, as well as pre-funded warrants to purchase up to 28,276,331 ordinary shares. The ordinary shares were sold to the purchasers at a price per ordinary share of €3.00 (corresponding to $3.22), and the pre-funded warrants at a pre-funded price of €2.90 (corresponding to $3.11) per pre-funded warrant, which equals the per share price for the ordinary shares less the remaining €0.10 exercise price for each such pre-funded warrant.

In April 2025, the Company completed a PIPE financing generating initial gross proceeds of $125.5 million (€116.3 million), followed by the full exercise of associated warrants in January 2026 after the announcement of positive Phase 3 VITESSE topline results, resulting in additional gross proceeds of $195.2 million (€166.7 million at 1 EUR = $1.17). The gross proceeds received subsequently of $94.2 million (€80.8 million at 1 EUR = $1.17) are not included in the table above.

In addition, in September 2025, the Company established an ATM equity program pursuant to which it may offer and sell up to $150.0 million of ADSs, subject to applicable regulatory limits. During the fourth quarter of 2025, the Company raised $65 million in gross proceeds through multiple issuances of ADSs.

The Company also benefits as an SME status from refunds of Research Tax credit (*crédit d’impôt recherche*) granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research.

Material expenses commitments

The following table presents our material expenses commitments for future periods:

	Material Cash Requirements Due by the Year Ended December 31,				
	2026	**2027**	**2028**	**Thereafter**	**Total**
	(Amounts in million)				
Operating leases	0.8	1.2	1.2	5.1	8.4
Purchase obligations - Obligations Under the Terms of CRO Agreements	26.6	22.0	22.1	19.1	89.8
Purchase obligations - Obligations Under the Terms of CMO Agreements	17.4	15.6	15.7	—	48.7
Total	**44.8**	**38.9**	**39.0**	**24.2**	**147.0**

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

Future events could cause actual payments to differ from these estimates.

Forward-looking

As a result of the proceeds received from the subsequent exercise of the ABSA and BS warrants of $94 million (€81 million) and with existing cash and cash equivalents as of December 31, 2025 of $194 million, management has determined that the Company has sufficient liquidity to fund its operations for at least twelve months from the date of issuance of this Form 10-K and that the conditions that previously raised substantial doubt about the Company's ability to continue as a going concern are no longer present. With the receipt of the aforementioned proceeds, and based on its current operations, plans, and assumptions, the Company estimates that its cash and cash equivalents are sufficient to fund its operations into the second quarter of 2027.

These estimates are based on the Company's current forecasts and exclude any additional expenditures related to other programs than the VIASKIN Peanut or resulting from the potential in licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue. The Company may have based these estimates on assumptions that are incorrect, and the Company may end up using its resources sooner than anticipated.

The Company may expend resources sooner than anticipated and may seek additional resources to execute the corporate strategy either through new or existing financing strategies. As of date of issuance, the remaining financing capacity and Equity securities are:

Remaining financing capacity and Equity securities	**Warrants**	**Strike price**	**Total Amount available**
2025 ATM Program			85.0
PFW1 from PFW-BS-PFW (2025 PIPE)	32,267,060	0.01	0.3
PFW2 (2025 PIPE)	67,688,140	0.02	1.4
PFW 2022	13,116,331	0.12	1.6
Total	**113,071,531**		**88.3**

Cash flows

The table below summarizes our sources and uses of cash for the years ended December 31, 2025 and 2024.

	December 31,		
(Amounts in thousands of U.S. Dollars)	**2025**	**2024**	**$ change**
Net cash flow used in operating activities	(121,181)	(104,474)	(16,707)
Net cash flow used in investing activities	(1,369)	(757.3)	(612.016)
Net cash flow provided by financing activities	276,182	587	275,596
Effect of exchange rate changes on cash and cash equivalents	8,080	(4,268)	12,348
Net (decrease) increase in cash and cash equivalents	**161,711**	**(108,913)**	**270,624**

Operating Activities

Our net cash flows used in operating activities were $121.2 million and $104.5 million for the years ended December 31, 2025 and 2024 respectively.

Our net cash flows used in operating activities increased by $16.7 million or 16%. The variance was primarily attributable to higher operating expenditures, including (1) expenses related to inventory (not capitalized) build-up to support commercial readiness, (2) increase in external clinical-related expenses driven by the initiation of patient recruitment for COMFORT Toddlers study and significant clinical milestone payments for VITESSE Study through the achievement of positive Topline results, and (3) higher personnel-related costs reflecting the full-year impact in 2025 of hires made in 2024, combined with additional hires in 2025 to support the BLA submission and commercial readiness, as well as certain non-recurring costs.

Investing Activities

Our net cash flows used in investing activities were $1.4 million in 2025 and $0.8 million in 2024.

Financing Activities

Our net cash flows resulting from financing activities was $276.2 million in 2025 compared to $0.6 million in 2024 resulting from successful financing operations completed by the company throughout the period as listed above in the section entitled **Financing of 2025 Year in review**.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with U.S. GAAP. Some of the accounting methods and policies used in preparing our financial statements under U.S. GAAP are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the facts and circumstances concerned. The actual value of our assets, liabilities and shareholders' equity and of our earnings could differ from the value derived from these estimates if conditions changed and these changes had an impact on the assumptions adopted. We believe that the most significant management judgments and assumptions in the preparation of our financial statements are described in **Note 1 to our financial statements for a description of our other significant accounting policies.**

March 2025 PIPE Financing

The accounting for the Company's pre-funded warrants issued in April 2025 involves significant judgment and represents a critical accounting estimate, as it requires management to determine whether the instruments should be classified as equity or liabilities, which could materially affect the Company's financial position and results of operations.

Management evaluated the pre-funded warrants under ASC 480, Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging, including the guidance in ASC 815-40, Contracts in Entity's Own Equity. This assessment required judgment in evaluating the contractual terms, settlement provisions and potential contingencies of the instruments.

The Company concluded that the pre-funded warrants do not meet the criteria for liability classification under ASC 480, as they are freestanding, provide for a fixed number of shares upon exercise, and do not obligate the Company to transfer cash or repurchase shares. In addition, management determined that the warrants are indexed to the Company's ordinary shares and qualify for equity classification under ASC 815-40, as they require physical settlement in shares, do not provide for net-cash settlement, and do not include cash-settled make-whole or similar provisions. The Company has sufficient authorized and unissued shares available to settle the warrants.

Accordingly, the pre-funded warrants are classified in permanent equity and are not remeasured at fair value after initial recognition. Subsequent changes in fair value are not recognized in earnings as long as the warrants continue to qualify for equity classification.

Upon exercise of the pre-funded warrants, the Company records the par value of the issued shares in common stock, and the remaining amount recorded in additional paid-in capital. No gain or loss is recognized upon exercise.

Share base payments

The Company maintains several share-based compensation plans for employees and non-employees. The accounting for share-based compensation represents a critical accounting estimate due to the significant judgment required to determine the fair value of equity awards at the grant date and the potential impact of changes in key assumptions on compensation expense and operating results.

Equity awards are measured at grant-date fair value and recognized as compensation expense, net of estimated forfeitures, over the requisite service period, which generally corresponds to the vesting period of the respective awards.

Valuation methodology and key assumptions

The fair value of stock options is estimated at the grant date using the Black-Scholes option pricing model, which requires management to make a number of highly subjective assumptions, including expected volatility, expected term, risk-free interest rate and expected dividend yield. These assumptions are inherently uncertain and require significant judgment.

- Exercise price of stock options is based on the fair market value of the Company's ordinary shares at the grant date.
- Risk-free interest rate is determined using French government bonds (GFRN) with a maturity corresponding to the expected term of the stock options.
- Expected term represents the period over which stock options are expected to remain outstanding and is determined based on the average expected life of the options, taking into account vesting conditions and historical exercise behavior.

- Expected volatility is determined based on historical share price data over a period consistent with the expected maturity of the stock options. Given the Company's exposure to factors such as clinical development progress, regulatory outcomes, financing activities and broader biotechnology market conditions, estimating future volatility involves a high degree of judgment.
- Expected dividend yield: The Company has never declared or paid cash dividends and does not currently intend to pay cash dividends in the foreseeable future. Accordingly, an expected dividend yield of zero is used in the valuation of stock options.

Sensitivity and impact on results of operations

Changes in the assumptions used to estimate the fair value of share-based awards could materially affect compensation expense. In particular, increases in expected volatility or expected term would generally result in a higher fair value of stock options and higher share-based compensation expense, while decreases in these assumptions would have the opposite effect. Share-based compensation expense is recognized primarily within research and development expenses and general and administrative expenses and therefore directly impacts the Company's operating loss. In addition, equity awards may result in future dilution to existing shareholders upon vesting and exercise.

Management reviews the assumptions used in valuing share-based awards on a regular basis and updates them as necessary based on available information. However, because these estimates depend on future events and market conditions, actual results may differ materially from management's estimates.

Smaller Reporting Company Status

We are a smaller reporting company as defined in the Securities Exchange Act of 1934, as amended. We may, and intend to, take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as we are a smaller reporting company. We may be a smaller reporting company in any year in which (i) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) (a) our annual revenue is less than $100.0 million during the most recently completed fiscal year and (b) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Off-Balance Sheet Arrangements

In connection with the launch of our clinical trials , we signed agreements with several CROs. As of December 31, 2025, expenses associated with the ongoing trials amounted globally to $32.7 million, and we had non-cancellable contractual obligations with CRO until the year ended 2027 amounting to $48.6 million.

The Company has entered into multi-year supply and manufacturing agreements that include minimum purchase obligations over defined periods. Under applicable accounting guidance, take-or-pay commitments are generally considered firm purchase commitments but remain off-balance sheet unless they create an unavoidable or unconditional payment obligation, or become loss contracts.

With Sanofi

On August 29, 2025, the Company entered into the Supply Agreement with SANOFI, under which SANOFI will manufacture and supply the Viaskin Peanut API for the Company. Under the Supply Agreement, the Company has agreed to certain minimum purchase levels and service fees over the initial 4-year-term.

As of December 31, 2025, total payments made during the period under the Supply Agreement are approximately $8.6M, which were recorded as R&D expenses. The Company will expense manufacturing and supply costs as incurred.

With Fareva

On March 17, 2026, DBV Technologies S.A. entered into a new Manufacturing and Supply Agreement (the "MS Agreement") with FAREVA La Vallée ("FLV"), under which the FLV will manufacture and supply the Viaskin Peanut Source Material ("PSM"), exclusively for DBV Technologies S.A. during the agreement term. The term is effective for a period of eight (8) years and can be renewed for a period of two (2) years .

As of December 31, 2025, total payments made during the year under the MS Agreement and the SBC Agreement are approximately $1.4 million, which were recorded as detailed in **Note 1 Nature of the business and principles and accounting methods, Significant contracts**.

The following table presents our material expenses commitments for future periods:

	2026	2027	2028	Thereafter	Total
			(Amounts in million)		
Purchase obligations - Obligations Under the Terms of CRO Agreements	26.6	22.0	22.1	19.1	89.8
Purchase obligations - Obligations Under the Terms of CMO Agreements	17.4	15.6	15.7	—	48.7
Total	**44.0**	**37.6**	**37.8**	**19.1**	**138.5**

Letter of Credit and Collateral

A Certificate of Deposit, for an initial amount of $0.3 million was signed in order to guarantee an American Express credit cards program in the United States.

Subsequent Events

March 2025 PIPE Financing - January 16, 2026

The Company has received the supplemental gross proceeds of $94 million (€81 million) resulting in the full exercise of the ABSA Warrants and BS Warrants issued on its March 2025 PIPE financing.

Additional Data from Successful Phase 3 VITESSE Study - February 28, 2026

The Company highlighted additional data from successful Phase 3 VITESSE Study at the AAAAI 2026 Annual Meeting

- Approximately 83% of children treated with the VIASKIN® Peanut Patch increased their eliciting dose at month 12, compared to approximately 48% in the placebo group;
- Approximately 60% of children treated with the VIASKIN® Peanut Patch increased their eliciting dose by at least two doses at month 12, compared to 23% in the placebo group;
- 24% of children on placebo decreased their eliciting dose between the baseline and month 12 double-blind, placebo-controlled food challenge, compared to only 6.4% of children treated with the VIASKIN® Peanut Patch.

Manufacturing Supply Agreement - PSM "Peanut Source Material " Fareva La Vallée - March 17, 2026

The Company entered into the MS Agreement with FLV, under which the CMO will manufacture and supply PSM, exclusively for DBV Technologies S.A. during the agreement term. The term is effective for a period of eight (8) years and can be renewed for a period of two (2) years.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), as appropriate, to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer evaluated the effectiveness of these disclosure controls and procedures and concluded that as of December 31, 2025, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Under the supervision and with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), management assessed the effectiveness of our internal control over financial reporting based upon the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the registrant's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

As a smaller reporting company, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting.

There were no changes to our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2025, none of our officers or directors (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Certain information required by Part III is omitted from this report because we will file with the SEC a definitive proxy statement pursuant to Regulation 14A, the Proxy Statement, and/or an amendment to this Form 10-K under cover of Form 10-K/A, the 10-K/A, no later than 120 days after the end of our fiscal year, and certain information included therein is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in the sections titled “Board of Directors and Corporate Governance,” “Information About Our Executive Officers,” “Code of Business Conduct and Ethics” and “Insider Trading Policy” in our Proxy Statement and is incorporated herein by reference.

We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver. The full text of our Code of Conduct is available at the Investor Overview—Corporate Governance section of our website at *www.dbv-technologies.com*. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report.

We have an insider trading policy governing the purchase, sale and disposition of our securities that applies to all of our personnel, including directors, officers, employees and other covered persons. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Form 10-K.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in the sections titled “Executive Compensation” (excluding the information under the subheading “Pay Versus Performance”) and “Board of Directors and Corporate Governance” in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in the sections titled “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in the sections titled “Board of Directors and Corporate Governance” and “Certain Relationships and Related Person Transactions” in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in the section titled “Audit Fees and Services” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

The financial statements schedules and exhibits filed as part of this Annual Report on Form 10-K are as follows:

(a)(1) Financial Statements

Reference is made to the financial statements included in Item 8 of Part II hereof.

(a)(2) Financial Statement Schedules

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
3.1*	By-laws (status) of the registrant (English translation)				
4.1	Form of Deposit Agreement	Form F-1/A	333-198870	4.1	10/15/2014
4.2	Form of Amendment No. 1 to Deposit Agreement	Form F-6 POS	333-266202	(a)(i)	05/17/2024
4.3	Form of Amendment No. 2 to Deposit Agreement	Form F-6 POS	333-266202	(a)(ii)	11/12/2024
4.4	Form of American Depositary Receipt	Form F-1/A	333-198870	4.1	10/15/2014
4.5	Description of Registered Securities	Form 20-F	001-36697	2.3	03/20/2020
4.6	Registration Rights Agreement, dated as of March 23, 2018, between the registrant, 667, L.P. and Baker Brothers Life Sciences, L.P.	Form 6-K	001-36697	4.1	03/23/2018
4.7	Registration Rights Agreement, dated as of June 8, 2022, between the registrant and the Investors named therein.	Form 8-K	001-36697	10.2	06/13/2022
4.8	Securities Purchase Agreement, dated as of June 8, 2022, between the registrant and the Subscribers named therein.	Form 8-K	001-36697	10.1	06/13/2022
4.9	Form of Securities Purchase Agreement	Form 8-K	001-36697	10.1	03/31/2025
4.10	Registration Rights Agreement, Dated March 27, 2025, by and between DBV Technologies S.A. and the investor parties thereto.	Form 8-K	001-36697	10.2	03/31/2025
10.1	Office Lease between the registrant and GENERALI VIE, dated March 3, 2025 (English translation)	Form 20-F	001-36697	4.2	04/29/2015
10.2*	Office Lease between the registrant and SCI DANTON MALAKOFF, dated October 2, 2023 (English translation)	Form 10-K	001-36697	10.2	03/07/2024
10.3*	Lease Agreement between DBV Technologies Inc. and SIG 106 LLC, dated March 28, 2022	Form 10-K	001-36697	10.3	03/07/2024
10.4	Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hopitaux de Paris and Université Paris Descartes, dated January 7, 2009 (English translation)	Form F-1	333-198870	10.2	09/22/2014
10.4#	Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016	Form 20-F	001-36697	4.14	03/22/2017
10.5#	Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 2018	Form 20-F	001-36697	4.5	04/01/2019
10.6*	Letter Agreement Terminating Development Collaboration and License Agreement between registrant and Société des Produits Nestlé S.A. (f/k/a NESTEC S.A.), dated October 26, 2023	Form 10-K	001-36697	10.6	03/07/2024
10.7†	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1/A	333-198870	10.3	10/15/2014
10.8†	2013 and 2014 Share Option Plans (English translation)	Form F-1/A	333-198870	10.4	09/22/2014

10.9†	2012, 2013 and 2014 Free Share Plans (English translation)	Form F-1/A	333-198870	10.5	09/22/2014
10.10†	Summary of BSA	Form F-1	333-198870	10.6	09/22/2014
10.11†	Summary of BSPCE	Form F-1	333-198870	10.7	09/22/2014
10.12†	2015 Share Option Plan (English translation)	Form 20-F	001-36697	4.10	04/28/2016
10.13†	2015 Free Share Plans (English translation)	Form 20-F	001-36697	4.11	04/28/2016
10.14†	2016 Share Option Plan (English translation)	Form 20-F	001-36697	4.12	03/22/2017
10.15†	2016 Free Share Plan (English translation)	Form 20-F	001-36697	4.13	03/22/2017
10.16†	2017 Share Option Plan (English translation)	Form 20-F	001-36697	4.14	03/16/2018
10.17†	2017 Free Share Plan (English translation)	Form 20-F	001-36697	4.15	03/16/2018
10.18†	2018 Share Option Plan (English translation)	Form 20-F	001-36697	4.17	04/01/2019
10.19†	2018 Free Share Plan (English translation)	Form 20-F	001-36697	4.18	04/01/2019
10.20†	2019 Share Option Plan (English translation)	Form 20-F	001-36697	4.19	03/20/2020
10.21†	2019 Free Share Plan (English translation)	Form 20-F	001-36697	4.20	03/20/2020
10.22†	2020 Share Option Plan (English translation)	Form 10-K	001-36697	10.21	03/17/2021
10.23†	2020 Free Share Plan (English translation)	Form 10-K	001-36697	10.22	03/17/2021
10.24†	2021 Share Option Plan (English translation)	Form 10-K	001-36697	10.22	03/09/2022
10.25†	2021 Free Share Plan (English translation)	Form 10-K	001-36697	10.23	03/09/2022
10.26†	2022 Share Option Plan (English translation)	Form 10-K	001-36697	10.24	03/02/2023
10.27†	2022 Free Share Plan (English translation)	Form 10-K	001-36697	10.25	03/02/2023
10.28†	2023 Share Option Plan (English translation)	S-8	333-275662	99.3	11/20/2023
10.29†	2023 Free Share Plan (English translation)	S-8	333-275662	99.2	11/20/2023
10.30†	2024 Share Option Plan (English translation)	S-8	333-280657	99.1	07/30/2024
10.31†	2024 Free Share Plan (English translation)	S-8	333-280657	99.2	07/30/2024
10.32†	2025 Stock Option Plan (English Translation)	S-8		99.1	06/24/2025
10.33†	2025 Free Share Plan (English Translation	S-8		99.2	06/24/2025
10.34†	Executive Agreement, dated November 29, 2018, between the registration and Daniel Tassé	Form 10-K	001-36697	10.23	03/17/2021
10.35†	First Amendment to the Executive Agreement of Daniel Tassé, dated June 27, 2019, between the registrant and Daniel Tassé	Form 10-K	001-36697	10.24	03/17/2021
10.36†	Executive Agreement, dated July 22, 2019, between the registrant and Pharis Mohideen	Form 10-K	001-36697	10.25	03/17/2021
10.37†	Letter Agreement, dated as of December 16, 2024, amending the Employment Agreement dated July 19, 2019, by and between registrant and Pharis Mohideen	Form 8-K	001-36697	10.1	12/16/2024
10.38†	Letter Agreement, dated June 26, 2019, between the registrant and Sébastien Robitaille (English translation)	Form 10-K	001-36697	10.26	03/17/2021
10.39†	Letter Agreement, dated December 1, 2019, between the registrant and Sébastien Robitaille (English translation)	Form 10-K	001-36697	10.26	03/17/2021
10.40*†	English Summary Translation of Separation Agreement and Release between Sébastien Robitaille and registrant	Form 10-K	001-36697	10.35	03/07/2024
10.341*†	Letter Agreement, dated November 1, 2023, between the registrant and Virginie Boucinha (English translation)	Form 10-K	001-36697	10.36	03/07/2024
10.42†	English Summary Translation of Letter Agreement dated as of December 16, 2024, amending the Employment Agreement dated November 6, 2023, by and between registrant and Virginie Boucinha	Form 8-K	001-36698	10.2	12/18/2024
10.43†	Executive Agreement, dated November 1, 2025, between the registrant and Kevin Trapp.				
10.44	Sales Agreement, dated as of September 5, 2025, by and between DBV Technologies S.A. and Citizens JMP Securities, LLC	Form 8-K	001-36697	1.1	09/05/2025
19.1*	Securities Trading Policy	Form 10-K	001-36698	19.1	04/11/2025
21.1*†	List of subsidiaries of the registrant	Form 10-K	001-36697	21.1	03/07/2024

23.1*	Consent of Deloitte & Associés					
23.2*	Consent of KPMG S.A.					
24.1**	Power of Attorney (included on the signature page of this report).					
31.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a- 14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					
31.2*	Certification of the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a- 14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					
32.1**	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					
97.1*	Incentive Compensation Recoupment Policy, approved	Form 10-K	001-36697	97.1	03/01/2024	
101.INS*	Inline XBRL Instance Document					
101.SCH*	Inline XBRL Taxonomy Extension Schema Document					
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					

* Filed herewith.
** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.
† Indicates a management contract or any compensatory plan, contract or arrangement.
# Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

Signatures

Pursuant to the requirements of Section 13 or 15(d) 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.

DBV Technologies S.A.

/s/ Daniel Tassé

Name: Daniel Tassé
Title: Chief Executive Officer
(Principal Executive Officer)

Date: March 26, 2026

Each person whose individual signature appears below hereby authorizes and appoints Daniel Tassé and Virginie Boucinha, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities indicated on March 26, 2026.

Signature	Title
/s/ Daniel Tassé Daniel Tassé	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Virginie Boucinha Virginie Boucinha	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Michel de Rosen Michel de Rosen	Director
/s/ Mailys Ferrere Mailys Ferrere	Director
/s/ Michael J. Goller Michael J. Goller	Director
/s/ Danièle Guyot-Caparros Danièle Guyot-Caparro	Director
/s/ Philina Lee Philina Lee	Director
/s/ Timothy E. Morris Timothy E. Morris	Director
/s/ Adora Ndu Adora Ndu	Director
/s/ Julie O'Neill Julie O'Neill	Director
/s/ Ravi Madduri Rao Ravi Madduri Rao	Director

Index to Financial Statements

Annual Financial Statements for the Years Ended December 31, 2025 and 2024:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Shareholders and Board of Directors of DBV Technologies S.A.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of DBV Technologies S.A. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, cash flows and changes in shareholders' equity for each of the years in the two-year period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are public accounting firms registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

PFW-BS-PFW – Refer to Note 1 to the consolidated financial statements

As disclosed in Note 1 to the consolidated financial statements, on April 7, 2025, the Company completed a financing consisting of (i) the issuance of 34,090,004 new shares with attached warrants (ABSA Warrants) for an amount of $41 million (€38 million) and (ii) the issuance of 71,005,656 units (PFW-BS-PFW) for an amount of $85 million (€79 million). Each PFW-BS-PFW unit comprised of one pre-funded warrant to subscribe to one share of the Company (First Pre-Funded Warrant) and one warrant (BS Warrant) to subscribe to one second pre-funded warrant (Second Pre-Funded Warrant). Management concluded that the April 2025 PFW-BS-PFW met the conditions required for equity classification.

We identified the assessment of the accounting classification of the PFW-BS-PFW instruments, including the First and Second Pre-Funded Warrants and related BS Warrants, as a critical audit matter. Challenging auditor judgment and specialized skills and knowledge were required in assessing whether the PFW-BS-PFW instruments should be accounted for as either liabilities or equity instruments due to the interpretation of contract provisions within the warrant agreements and application of complex technical accounting guidance.

The following are the primary procedures we performed to address this critical audit matter. We involved professionals with specialized skills and knowledge, who assisted in reading the underlying agreements to understand the relevant contract provisions and in evaluating whether the Company's accounting classification of PFW-BS-PFW instruments, including the First and Second Pre-Funded Warrants and related BS Warrants, was in accordance with the relevant complex technical accounting guidance.

/s/ Deloitte & Associés

We have served as the Company's auditor since 2011.

KPMG S.A.

/s/ Renaud Maxime Cambet

Partner

We have served as the Company's auditor since 2020.

Paris-La Défense, France
March 26, 2026

DBV Technologies S.A.

Consolidated Statements of Financial Position

(amounts in thousands, except share and per share data)

	Note		December 31, 2025	December 31, 2024
Assets				
Current assets :				
Cash and cash equivalents	**3**	$	194,167	32,456
Other current assets	**4**		18,776	11,932
Total current assets			**212,943**	**44,388**
Property, plant, and equipment, net	**5**		10,370	11,306
Right-of-use assets related to operating leases	**6**		4,575	5,502
Intangible assets			22	40
Other non-current assets	**7**		5,809	4,423
Total non-current assets			**20,775**	**21,271**
Total Assets		**$**	**233,718**	**65,658**
Liabilities and shareholders' equity				
Current liabilities:				
Trade payables	**8**	$	40,941	22,032
Short-term operating leases	**6**		1,117	654
Current contingencies & Employee Benefits	**12**		217	122
Other current liabilities	**8**		15,750	8,328
Total current liabilities			**58,025**	**31,136**
Long-term operating leases	**6**		5,409	6,297
Non-current contingencies & Employee Benefits	**12**		1,513	838
Total non-current liabilities			**6,923**	**7,135**
Total Liabilities		**$**	**64,948**	**38,271**
Shareholders' equity :				
Ordinary shares €0.1 par value; 235,670,864 and 102,847,501 shares authorized, and issued as at December 31, 2025 and December 31, 2024, respectively,		$	26,912	11,651
Additional paid-in capital			541,251	315,613
Treasury stock, 74,680 and 266,868 ordinary shares as of December 31, 2025 and December 31, 2024, respectively, at cost			(834)	(1,309)
Accumulated deficit			(393,129)	(286,375)
Accumulated other comprehensive income			497	905
Accumulated currency translation effect			(5,927)	(13,097)
Total Shareholders' equity		**$**	**168,770**	**27,387**
Total Liabilities and Shareholder's equity	**10**	**$**	**233,718**	**65,658**

The accompanying notes are an integral part of these consolidated financial statements.

DBV Technologies S.A.

Consolidated Statements of Operations and Comprehensive Loss

(amounts in thousands, except share and per share data)

	Notes		Twelve Months Ended December 31, 2025	2024
Operating income	**13**		**5,636**	**4,151**
Operating expenses				
Research and development expenses			(116,682)	(89,342)
Sales and marketing expenses			(3,222)	(2,659)
General and administrative expenses			(32,788)	(28,739)
Total Operating expenses	14		**(152,692)**	**(120,740)**
Loss from operations			**(147,056)**	**(116,589)**
Financial income (expense)			601	2,726
Loss before taxes			**(146,456)**	**(113,863)**
Income tax	15		(491)	(55)
Net loss		**$**	**(146,947)**	**(113,918)**
Foreign currency translation differences, net of taxes			7,170	(4,222)
Actuarial gains on employee benefits, net of taxes			(408)	163
Comprehensive loss		$	**(140,185)**	**(117,977)**
Basic/diluted Net loss per share attributable to shareholders	**18**	**$**	**(1.05)**	**(1.17)**
Weighted average shares outstanding used in computing per share amounts:			139,574,259	96,995,379

The accompanying notes are an integral part of these consolidated financial statements.

DBV Technologies S.A.

Consolidated Statements of Cash Flows

(amounts in thousands)

	Notes		Twelve Months Ended December 31, 2025	2024
Net loss for the period		**$**	**(146,947)**	**(113,918)**
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation, amortization and accrued contingencies			3,194	(925)
Expenses related to share-based payments			5,387	4,620
Inventory write-downs	14		16,062	1,388
Other elements			(219)	(3)
Changes in operating assets and liabilities:				
Decrease (increase) in inventories and work in progress			(16,062)	(1,388)
Decrease (increase) in other current assets	4		(4,699)	4,629
(Decrease) increase in trade payables	8		15,783	272
(Decrease) increase in other current and non-current liabilities	8		6,521	366
Change in operating lease liabilities and right of use assets			(203)	485
Net cash flow used in operating activities			**(121,181)**	**(104,474)**
Cash flows used in investing activities :				
Change in property, plant, and equipment	5		(532)	(2,338)
Change in intangible assets			(6)	(3)
Change in non-current other assets	7		(831)	1,584
Net cash flows used in investing activities			**(1,369)**	**(757)**
Cash flows provided by financing activities :				
Treasury shares			476	(47)
Capital increases, net of transaction costs	10		275,706	634
Net cash flows provided by financing activities			**276,182**	**587**
Effect of exchange rate changes on cash and cash equivalents			8,080	(4,268)
Net (decrease) / increase in cash and cash equivalents			**161,711**	**(108,913)**
Net Cash and cash equivalents at the beginning of the period			32,456	141,367
Net cash and cash equivalents at the end of the period		**$**	**194,167**	**32,456**

The Company now presents inventory write-downs separately from the “Decrease (Increase) in inventories and work in progress” line item. Comparative information has been updated accordingly to ensure consistency.

The accompanying notes are an integral part of these consolidated financial statements.

DBV Technologies S.A.

Consolidated Statements of Changes in Shareholders' Equity

(amounts in thousands, except share and per share data)

	Ordinary shares							
	Number of Shares	Amount	Additional paid-in capital	Treasury stock	Accumulated deficit	Accumulated other comprehensive income (loss)	Accumulated currency translation effect	Total Shareholders' Equity
Balance at December 31, 2023	**96,431,770**	**10,972**	**377,468**	**(1,263)**	**(238,862)**	**742**	**(8,871)**	**140,187**
Net (loss)	—				(113,918)			(113,918)
Other comprehensive income (loss)	—					163	(4,222)	(4,059)
Issuance of ordinary shares	405,731	43	(43)					
Issuance of warrants	6,010,000	636						636
Treasury shares	—			(47)				(47)
Share-based payments	—		4,620					4,620
Allocation of accumulated net losses	—		(66,433)		66,433			
Other change in equity	—				(28)		(4)	(32)
Balance at December 31, 2024	**102,847,501**	**11,651**	**315,613**	**(1,309)**	**(286,375)**	**905**	**(13,097)**	**27,387**
Net (loss)	—				(146,947)			(146,947)
Other comprehensive income (loss)	—					(408)	7,170	6,762
Issuance of ordinary shares	132,823,363	15,261	190,391					205,652
Issuance of warrants			70,053					70,053
Treasury shares	—			476				476
Share-based payments	—		5,387					5,387
Allocation of accumulated net losses	—		(40,193)		40,193			
Other change in equity	—							
Balance at December 31, 2025	**235,670,864**	**26,912**	**541,251**	**(834)**	**(393,129)**	**497**	**(5,927)**	**168,770**

The accompanying notes are an integral part of these consolidated financial statements.

Notes to the Consolidated Financial Statements

Note 1 Nature of the business and principles and accounting methods

Incorporated in 2002 under the laws of France, DBV Technologies S.A. (“DBV Technologies,” or the “Company”, or “we”, or the “group”) is a late-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin. The Company’s therapeutic approach is based on EPIT, a proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin.

Basis of Presentation

The Company’s consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the U.S. (“U.S. GAAP”) and presented in thousands of U.S. Dollars, except for share and per share data and as otherwise noted. Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). We also follow the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). The Consolidated Financial Statements have been prepared assuming the Company will continue as a going concern and using the historical cost principle with the exception of certain assets and liabilities that are measured at fair value in accordance with U.S. GAAP. The categories concerned are detailed in the following notes.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances transparency by requiring additional disclosures related to income taxes. The amendments primarily require:

- A tabular reconciliation of the effective tax rate to the statutory rate, including both dollar amounts and percentages, with separate disclosure of items that are equal to or greater than 5% of the statutory rate.
- Disaggregation of income taxes paid between federal, state, and foreign jurisdictions, and identification of any individual jurisdiction that accounts for 5% or more of total income taxes paid.

The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company applied the ASU retrospectively by providing the revised disclosures for the year ended December 31, 2024.

Accounting Pronouncements issued not yet adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income Topic 220 — Expense Disaggregation Disclosures. The guidance requires disclosure of additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. The disclosure requirements will be applied on a prospective basis, with the option to apply it retrospectively. For SEC filers, this ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Management evaluated the impact of adopting ASU 2024-03 and determined that its adoption will result on expanded disclosures on the Company’s consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements, which includes a series of technical corrections, clarifications, and minor improvements to existing guidance across various Topics in the FASB Accounting Standards Codification. The amendments are not expected to significantly affect current accounting practices. ASU 2025-12 is effective for annual and interim reporting periods beginning after December 15, 2026. The Company does not expect the adoption of this ASU to have a material impact on its consolidated financial statements.

In December 2025, the FASB also issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements, which clarifies the scope and applicability of interim reporting guidance, enhances the organization and navigability of required interim disclosures, and introduces a disclosure principle requiring entities to disclose material events or changes that occur after the most recent annual reporting period. For public business entities, the ASU is effective for interim reporting periods in fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this ASU on its interim reporting disclosures and does not expect it to have a material impact on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities, which establishes authoritative U.S. GAAP guidance for the recognition, measurement, presentation, and disclosure of government grants received by business entities. The amendments are effective for public business entities for annual reporting periods beginning after December 15, 2028, including interim periods within those annual periods, with early adoption permitted. The Company is evaluating the potential impact of adopting this guidance on its consolidated financial statements. However, it does not expect a material impact.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company’s Consolidated Financial Statements upon adoption.

Use of estimates

The preparation of the Company's consolidated financial statements requires the use of estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of income and expenses during the period. The estimates and assumptions, developed based on the information available at the time of closing the accounts, particularly relate to:

- The assessment of the fair value of equity-settled share-based compensation plans granted to employees and/or executives, which is performed using actuarial models. These models require the Company to use certain calculation assumptions, such as the expected volatility of the share price and the estimated timing of achieving performance conditions over the vesting period of the share-based compensation plan ;
- The evaluation of the amount of the Research Tax Credit, which is based on eligible internal and external research expenses incurred by the Company during the fiscal year. Only eligible research expenditures are included in the calculation of the Research Tax Credit;
- The recoverability of the Company's net deferred tax assets and related valuation allowance
- The assumptions used in the valuation of right-of-use assets & operating leases
- The estimate of provisions and contingencies.

The final amounts may differ from these estimates. Management is also required to exercise judgment in the following areas:

Going concern

These Consolidated Financial Statements have been prepared assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business for at least twelve months as of date of issuance of the Financial statements. The Company has incurred operating losses and negative cash flows from operations since inception. The Company does not generate revenue and continues to prepare for the potential launch of its first product in the United States and in the European Union, if approved.

In April 2025, the Company completed a PIPE financing generating initial gross proceeds of $125.5 million (€116.3 million), followed by the full exercise of associated warrants in January 2026 after the announcement of positive Phase 3 VITESSE topline results, resulting in additional gross proceeds of $195.0 million (€166.7 million).

In addition, in September 2025, the Company established an ATM equity program pursuant to which it may offer and sell up to $150.0 million of ADSs, subject to applicable regulatory limits. During the fourth quarter of 2025, the Company raised $65 million in gross proceeds through multiple issuances of ADSs.

As a result of the proceeds received from the subsequent exercise of the ABSA and BS warrants of $94 million (€81 million) and with existing cash and cash equivalents as of December 31, 2025 of $194 million, management has determined that the Company has sufficient liquidity to fund its operations for at least twelve months from the date of issuance of this Form 10-K and that the conditions that previously raised substantial doubt about the Company's ability to continue as a going concern are no longer present. With the receipt of the aforementioned proceeds, and based on its current operations, plans, and assumptions, the Company estimates that its cash and cash equivalents are sufficient to fund its operations into the second quarter of 2027.

These estimates are based on the Company's current forecasts and exclude any additional expenditures related to other programs than the VIASKIN® Peanut or resulting from the potential in licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue. The Company may have based these estimates on assumptions that are incorrect, and the Company may end up using its resources sooner than anticipated.

Significant contracts

March 2025 PIPE Financing

Financing Milestones

On March 27, 2025, the Company announced the 2025 PIPE financing, to advance the VIASKIN Peanut patch through BLA submission and U.S. commercial launch, if approved.

The financing included gross proceeds of $125.5 million (€116.3 million) received on April 7, 2025, and up to $181.4 million (€168.2 million at the exchange rate of 1 EUR = $1.08) in potential additional gross proceeds contingent to the full exercise of all the warrants, subject to satisfaction of specified conditions. The VITESSE Phase 3 study hitting its primary endpoint will trigger an acceleration of the exercise period of some of the warrants. The ABSA Warrants (defined below) will be exercisable from their respective date of issue until the earlier of (i) April 7, 2027 and (ii) 30 days following the publication by the Company of a press release announcing that the ongoing VITESSE trial of the VIASKIN® Peanut patch in children 4-7 years old met the primary endpoint defined in the VITESSE study protocol (the "Vitesse Topline Results"). It being specified that (i) the primary measure of treatment effect will be the difference in response rates at Month 12 between active and placebo treatment groups, (ii) the primary analysis will be based on a 2-sided confidence interval ("CI") for the difference in response rates, and (iii) the primary analysis must be positive according to the success criterion (lower bound of the 2-sided 95% CI of the difference in response rates ≥ 15%) (the "ABSA Warrant Exercise Period").

Following the announcement of the positive VITESSE Topline Results on December 16, 2025, the ABSA Warrants and BS Warrants were exercisable until January 16, 2026. On January 16, 2026, the Company announced additional gross proceeds of €166.7 million resulting from the full exercise of (i) 34,090,004 warrants attached to the ABSA Warrants (as defined below) resulting in the issuance of 59,657,507 new ordinary shares of the Company (as defined below) and (ii) 71,005,656 BS Warrants (as defined below) resulting in the issuance of 71,005,656 Second Pre-Funded Warrants (as defined below), allowing its holders to subscribe for an aggregate of up to 124,259,898 new shares.

On January 16, 2026, the Company announced additional gross proceeds of $195.0 million (€166.7 million at the exchange rate of 1 EUR = $1.17) resulting from the full exercise of the ABSA Warrants and BS Warrants, following the announcement of the positive VITESSE Topline Results on December 16, 2025. Of these proceeds, $100.7 million in gross proceeds (€85.7 million, at the exchange rate of 1 EUR = $1.17) was received as of December 31, 2025, with the remaining amount received in January 2026.

Reminder of the main characteristics of the financing

The exercise of one (1) ABSA Warrant gives the holder the right to subscribe to one point seventy-five (1.75) ABSA Warrant Shares at a price of €1.5939 per ABSA Warrant. The financing resulted in an immediate dilution of 22.4% and a maximal dilution of up to 73.7% of existing shareholders (on a non-diluted basis) if all the warrants in the Offering are exercised in full. The financing consisted of:

- a share capital increase without preferential subscription rights reserved to categories of persons satisfying determined characteristics pursuant to the 24th resolution of the 2024 General Meeting completed on April 7, 2025 for an amount of $41 million (€38 million), consisting of the issuance of (i) 34,090,004 new shares at a par value of €0.10 (the "New Shares") each with warrants of the Company attached (the "ABSA Warrants", and together with the New Shares, the "ABSA") at a subscription price of €1.1136 per ABSA and (ii) up to 59,657,507 additional new shares, if all the ABSA Warrants attached to the New Shares are exercised (the "ABSA Warrant Shares");
- and the issue through an offering reserved to categories of persons satisfying determined characteristics of 71,005,656 units (the "PFW-BS-PFW") completed on April 7, 2025 for an amount of $85 million (€79 million) at a subscription price of €1.1136 per PFW-BS-PFW (of which €1.1036 will have been prefunded on the issue date), each PFW-BS-PFW consisting of one pre-funded warrant to subscribe for one share of the Company (the "First Pre-Funded Warrants") and one warrant (the "BS Warrants") to subscribe to one second pre-funded warrants (the "Second Pre-Funded Warrants"), each of which entitles the holder to subscribe for 1.75 shares of the Company (the "Second PFW Shares"), allowing to issue up to 71,005,656 additional new shares if all the First Pre-Funded Warrants are exercised (the "First PFW Shares") and up to 124,259,898 additional new shares if all the Second Pre-Funded Warrants are exercised (the "Second PFW Shares", together with the ABSA Warrant Shares and the First Pre-Funded Warrant Shares, the "Warrant Shares", and together with the New Shares, the "Offered Shares"),(together, the "Offering").

Use of proceeds

The proceeds from the issue of the ABSA Warrants and BS Warrants, together with existing cash and cash equivalents, will be mainly used (i) for working capital and general corporate purposes, (ii) to finance the preparation and submission of a potential Biologics License Application (BLA) as well as (iii) efforts to support, the readiness of the potential launch of VIASKIN® Peanut for children aged 4-7 years in the US, if approved.

Accounting treatment

To properly account for pre-funded warrants under US GAAP, an issuer must first apply ASC 480 – Distinguishing liabilities from equity, and then from ASC 815 – Derivatives and Hedging ASC 480 – DISTINGUISHING LIABILITIES FROM EQUITY

Under ASC 480–10–25, a financial instrument should be classified as liability if:

(i) It is mandatorily redeemable,

(ii) It represents an unconditional obligation to repurchase the issuer's equity shares,

(iii) It requires the issuer to deliver a variable number of shares or net cash settlement.

In our view, April 2025 prefunded warrants avoid all ASC 480 triggers as they meet the following conditions:

(i) Freestanding and detachable: they are legally separable from other instruments,

(ii) Fixed exercise terms: they entitle the holder to a fixed number of shares upon exercise,

(iii) No redemption obligations: they do not require the issuer to transfer cash to repurchase shares.

ASC 815 – DERIVATIVES AND HEDGING

ASC 815 – 40 – Contracts in Entity's Own Equity addresses whether an equity-linked contract, qualifies as equity in the entity's financial statements. Indexation to the Company's own stock. The first condition that must be met for an equity-linked instrument to qualify as equity is to be considered indexed to the entity's own stock in accordance with ASC 815-40-15. To determine whether an equity-linked instrument is indexed to the Entity's own stock, a 2-step analysis must be performed:

- Step 1 – Evaluate whether the instrument contains any exercise contingencies, and, if so, whether they disqualify the instrument from being classified as equity,
- Step 2 – Assess whether the settlement terms are consistent with equity classification.

Based on the above elements Prefunded warrants are to be indexed to the Company's stock.

Equity classification

As Pre-Funded warrants require a settlement in shares (physical settlement) and neither give rise to a net-cash settlement nor provide the option of settlement in shares or net cash settlement, they shall be initially classified as equity. Other conditions necessary for equity classification are met:

- The Company has sufficient authorized and unissued shares available to settle the contract after considering all other commitments that may require the issuance of stock during the maximum period the Pre-Funded warrants could remain outstanding.
- The contract contains an explicit limit on the number of shares (1 share per First Pre-Funded warrant and up to 71,005,656 in total and 1.75 share per Second Prefunded warrant and up to 124,259,898 in total) to be delivered in a share settlement. Adjustments to the exercise ratio are subject to the occurrence of specific events and result from the application of determined formulas.
- There is no required cash payment if DBV Technologies S.A. fails to timely file. There is no requirement to net cash settle the contract in the event the entity fails to make timely filings with the SEC or to maintain registration.
- There are no cash settled top-off or make-whole provisions. April 2025 Prefunded warrants can be classified as equity and shall be accounted for in permanent equity. Subsequent changes in fair value shall not be recognized as long as they continue to be classified as equity.

Upon exercise of the pre-funded warrants, the Company issued common shares in accordance with the terms of the warrants. The accounting treatment for the exercise is as follows:

- The par value of the newly issued common shares is recorded in 'Common stock'. Any additional amount, including the exercise price paid and the remaining carrying amount of the warrants is recorded in 'Additional paid-in capital.
- No gain or loss was recognized in the Consolidated Statements of Operations and Comprehensive Loss as the warrants were classified as equity from inception.
- The Company updated its share count and equity roll-forward to reflect the issuance of shares.

Manufacturing Supply Agreement - PSM "Peanut Source Material " Fareva La Vallée

On March 17, 2026, DBV Technologies S.A. entered into the MS Agreement with FLV, under which FLV will manufacture and supply the PSM, exclusively for DBV Technologies S.A. during the agreement term. The term is effective for a period of eight (8) years and can be renewed for a period of two (2) years.

This contract is subsequent to the initial PSM Service Agreement entered into on March 18, 2024 by the Company and FLV for the construction of a dedicated facility (PSM Facility) and the transfer of manufacturing of the PSM required to produce Viaskin Peanut patches. This contract also included binding commercial terms which were incorporated into the MS Agreement.

The PSM Services Agreement services include (i) construction activities, (ii) the acquisition equipment, and (iii) the cGMP qualification of a dedicated PSM production line installed at FLV's premises. DBV has funded capital expenditures amounting to $3.9 million, granting access to preferential pricing and to an exclusively dedicated PSM production line located at FLV's facilities, while ownership of the line remains with FLV. The assessment of the Master Supply Agreement concludes that the arrangement contains an embedded lease within the scope of ASC 842 (Leases), based on the following criteria:

- *Identified asset:* The dedicated PSM production line represents an identified asset, and the supplier does not have substitution rights.
- *Control of use:* The Company has (i) the right to obtain substantially all of the economic benefits from use of the asset, through exclusive access to the production capacity, and (ii) the right to direct the use of the asset, including decision-making authority over relevant activities such as production volumes, scheduling, and operating methods.

In accordance with ASC 842-10-25-2, the right-of-use asset will be recognized at the lease commencement date, defined as the date on which the production line is made available for use following completion of cGMP qualification. As the lease commencement date occurs in 2026, no recognition or reclassification is required for FY2025. The disclosure has therefore been limited to describing the accounting treatment upon commencement. In accordance with ASC 855 (Subsequent Events), the year-end assessment is limited to the identification of the embedded lease, the separation of lease and non-lease components of the arrangement, and the reclassification of the payment related to the exclusive access right as prepaid rent under ASC 842.

The Company has non-cancellable minimum commitments for PSM, subject to the terms of the MS Agreement. At the end of a 36-month period starting from the first commercial batch delivery, if the Company has not ordered any batches, excluding technical and validation batches, the Company shall pay FLV an amount not to exceed $0.6 million.

Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated.

The following list presents all entities included in the consolidation scope for the years ended December 31, 2024 and 2025, as well as their country of incorporation and the percentage of ownership interests:

- DBV Technologies Inc. was incorporated in Delaware on April 7, 2014 (the “U.S. subsidiary”). The share capital of this U.S. subsidiary is 100% owned by DBV Technologies S.A.;
- DBV Australia Pty Ltd. was incorporated in New South Wales, Australia on July 3, 2018 (the “Australian subsidiary”). The share capital of this Australian subsidiary is 100% owned by DBV Technologies S.A.;
- DBV Pharma was incorporated in Paris on December 31, 2018 (the “French subsidiary”). The share capital of this French subsidiary is 100% owned by DBV Technologies S.A.

Foreign Currency Matters

Functional Currency and Translation of Financial Statements in Foreign Currency

The Consolidated Financial Statements are presented in U.S. dollars, which differs from the functional currency of the Company, being the Euro. The statements of financial position of consolidated entities having a functional currency different from the presentation currency are translated at the closing exchange rate (spot exchange rate at the statement of financial position date) and the statements of operations, statements of comprehensive loss and statements of cash flow of such consolidated entities are translated at the weighted average exchange rate. The resulting translation adjustments are included in equity under the caption “Accumulated other comprehensive income (loss)” in the Consolidated Statements of Changes in Shareholders’ Equity.

Conversion of Foreign Currency Transactions

Foreign currency transactions are converted to functional currency of the entity at the rate of exchange applicable on the transaction date. At period-end, foreign currency monetary assets and liabilities are converted at the rate of exchange prevailing on that date. The resulting exchange gains or losses are recorded in the Consolidated Statement of Operations and Comprehensive Loss in Operating income (expenses) or Financial income (expenses) depending on the nature of the underlying monetary item.

Intangible Assets

Acquired intangible assets are accounted for at acquisition cost less accumulated amortization. Acquired intangible assets are mainly composed of software amortized on a straight-line basis over their estimated useful lives comprised between one and three years. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The costs related to the acquisition of licenses to software are posted to assets on the basis of the costs incurred to acquire and to implement the software.

Research and Development Expenditures

Research and development expenditures are charged to expense as costs are incurred in performing research and development activities. Research and development costs include all direct costs, including salaries, share-based payments and benefits for research and development personnel, outside consultants, costs of clinical trials, costs related to manufacturing clinical study materials, sponsored research, clinical trials insurance, other outside costs, depreciation, and facility costs related to the development of drug candidates. The Company records upfront, non-refundable payments made to outside vendors, or other payments made in advance of services performed or goods being delivered, as prepaid expenses, which are expensed as services are performed or the goods are delivered.

Lease contracts

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. The Company’s leases are comprised of real estate leases, leases for industrial equipment and leases for office equipment.

The Company’s real estate leases typically include options and features including rent free periods, rent escalation periods, renewal options and early termination options. The lease term is defined contract-by-contract and corresponds to the non-cancelable period of the lease taking into account the optional periods that are reasonably certain to be exercised.

The Company recognizes operating lease liabilities based on the present value of the future minimum lease payments over the lease term at commencement date.

The Company does not recognize a lease liability or right of use asset for leases with a term of 12 months or less. Operating lease right of use assets are presented as operating lease right of use assets on the consolidated balance sheet. To date, the Company has recognized a single lease cost under which the operating lease right of use and liability are amortized on a straight-line basis over the lease term, and categorized within Operating Expense in the Consolidated Statement of Operations. The operating lease cash flows are categorized under Net Cash Used in Operating Activities in the Consolidated Statement of Cash Flows. Variable costs are expensed in the period incurred.

Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rates based on the information available at commencement date in determining the discount rate used to calculate the present value of lease payments. As the Company has no external borrowings, the incremental borrowing rates are determined using information on indicative borrowing rates that would be available to the Company based on the value, currency and borrowing term provided by financial institutions, adjusted for company and market specific factors.

Property, Plant, and Equipment

Property, plant, and equipment are recorded at their acquisition cost.

Property, plant, and equipment are depreciated on a straight-line method over the estimated useful lives of the property. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the remaining lease term.

Depreciation is calculated on a straight-line basis over the assets' estimated useful lives as follows:

Property, plant, and equipment item period	Depreciation
Laboratory equipment and technical facilities	3 to 10 years
Building fixtures and leasehold improvements	5 to 9 years
Office equipment and furniture	5 years
Computer equipment	3 years

Impairment of assets

The Company periodically reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable or the estimated useful life is no longer appropriate. If indicators of impairment exist and the recoverable value of the asset on an undiscounted cash flow basis is less than the carrying amount, an impairment loss is recorded to the extent the carrying amount exceeds its fair value.

Financial Instruments

The following section details the principles applicable to non-derivative and derivative financial instruments, with a focus on classification, measurement, and impairment.

Non-Derivative Financial Assets: Classification and Measurement

Financial assets that are not derivatives are classified based on management's intent and the asset's characteristics. The company has mainly deposits and receivables that are not securities that are typically measured at amortized cost, less any allowance for credit losses.

Non-Derivative Financial Liabilities: Classification and Measurement

Financial liabilities that are not derivatives are initially recognized at fair value, net of transaction costs directly attributable to the issuance. Subsequent measurement is generally at amortized cost using the effective interest method. If a liability is designated as held for trading or accounted for under the fair value option (ASC 825), it is measured at fair value, with changes recognized in earnings. Interest expense on financial liabilities is recognized in the income statement.

Derivative Financial Instruments: Recognition and Measurement

All derivative instruments are recognized initially at fair value, with subsequent changes in fair value recognized in earnings unless the derivative qualifies for hedge accounting under ASC 815. For qualifying hedges, the accounting treatment depends on the type of hedge (fair value, cash flow, or net investment). Derivatives not designated as hedging instruments are measured at fair value with gains and losses reported in earnings, typically within other income or expense. Transaction costs directly attributable to derivatives are expensed as incurred.

Fair Value Measurements

Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Level 1—Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date;
- Level 2—Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined through the use of models or other valuation methodologies;
- Level 3—Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. The Company's policy is to recognize transfers between levels of the fair value hierarchy in the period the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, 2, or 3 during the periods presented.

Inventories and Work in Progress

Under ASC 330, Inventories are measured at the lower of cost or net realizable value, and any write-downs are permanent. The cost of inventories includes:

- Acquisition costs of raw materials,
- Conversion costs (including services and indirect costs),
- Other costs incurred to bring the inventories to their present location and condition.

The Company applies the weighted average cost method at period-end for inventory valuation. This approach calculates a weighted average cost of the items available at the end of each period, ensuring consistent valuation of production batches.

The Company also uses standard cost for analytical tracking and industrial management. Variances between standard costs and actual costs, which flow through profit or loss, are analyzed and allocated to inventories when significant.

Inventories mainly consist of work in progress related to the production of initial batches intended for commercialization.

As the company is currently under Phase 3 of its clinical development and awaiting regulatory approvals, all pre-commercial inventories have been fully written down. Reversals of inventory write-downs are prohibited, even if inventories are subsequently sold.

Cash and Cash Equivalents

Cash includes cash on hand and demand deposits with banks. Cash equivalents include short-term, highly liquid investments, with a short term remaining maturity at the date of purchase or less, readily convertible to known amounts of cash, for which the risk of changes in value is considered to be insignificant. Demand deposits therefore meet the definition of cash equivalents. Cash equivalents are measured at fair value using Level 1 and any changes are recognized in the Consolidated Statements of Operations and Comprehensive Loss.

Share Capital

Ordinary shares are classified under Shareholders' Equity. The costs of share capital transactions that are directly attributable to the issue of new shares or options are recorded in the Consolidated Financial Statements in Shareholders' Equity as a deduction from the proceeds from the issue, net of tax.

Share-based payments

In accordance with U.S. GAAP, specifically ASC 718, Compensation—Stock Compensation, these awards are measured at their fair value on the date of grant. The fair value is amortized in personnel expenses (allocated by function in the Consolidated Statements of Operations and Comprehensive Loss) on a straight-line basis over the requisite service (vesting) period typically four years, with a corresponding increase in shareholders' equity. The expense measurement also takes into account the level of achievement of performance conditions, where applicable and on the legal interpretation of the RSUs award agreements with employees under the French labor laws and related jurisprudence. Changes in interpretations could significantly impact on the accounting for the share-based payments.

Since its incorporation, the Company has established several plans for equity compensation issued in the form of employee warrants (bons de souscription de parts de créateur d'entreprise or "BCEs"), stock options ("SO"), and restricted stock units ("RSUs") granted to employees and/or executives. The company has also established several plans for equity compensation issued in the form of "share warrants" (bons de souscription d'actions or "BSAs") granted to non-employee members of the Board of Directors and members of the Scientific Advisory Board.

Stock Option Plans ("SO")

The fair value of stock option plans is measured at the grant date using Black and Sholes models that require inputs based on certain subjective assumptions, including the expected term of the award, and the conditions of each equity plan. The expense recognized reflects the estimated forfeiture rate of the options. This expense is adjusted over the vesting period to reflect the actual forfeiture rate due to departures and the achievement of non-market performance criteria.

At each closing date, the Company reassesses the number of options expected to vest. If applicable, the impacts of such revised estimates are recognized in the Consolidated Statements of Operations and Comprehensive Loss, with a corresponding adjustment in shareholders' equity. The awards are not subject to any market conditions.

Restricted Stock Unit Plans ("RSU")

The fair value of the granted shares is based on the market price of the Company's stock at the grant date. Other conditions are considered in estimating the number of shares expected to vest during the vesting period, and this number is finally adjusted based on the actual number of shares vested at the vesting date.

Government grants and conditional advances

The Company benefits from various forms of government assistance, including grants and conditional advances.

In the absence of specific authoritative guidance under U.S. GAAP applicable to for-profit entities, the Company accounts for government grants by analogy to *IAS 20 Accounting for Government Grants and Disclosure of Government Assistance*, which management believes provides the most relevant and reliable accounting framework.

Government grants are recognized when there is reasonable assurance that:

- the Company will comply with the conditions attached to the grants; and
- the grants will be received.

Non-refundable grants are initially recorded as deferred income and are recognized in the statement of operations as "Other operating income" on a systematic basis over the period of the related research program to which the grants relate.

A government grant receivable that is intended either to compensate for expenses or losses already incurred, or to provide immediate financial support to the Company with no future related costs, is recognized in income in the period in which the receivable becomes earned and realizable.

Research Tax Credit specific considerations

The research tax credit (*crédit d'impôt recherche*) is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria receive a tax credit that can be used against the payment of the income tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the Research Tax Credit involve only research expenses.

In the fiscal year ended December 31, 2021, the Company recovered its Small and Medium-sized Enterprises ("SMEs") status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit.

Contingencies

An estimated loss from a loss contingency is recognized if the following two conditions are met:

- information available before the consolidated financial statements are issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the consolidated financial statements; and
- the amount of loss can be reasonably estimated.

With respect to litigations and claims that may result in a liability to be recognized, we exercise significant judgment in measuring and recognizing a liability or determining exposure to contingent liabilities that are related to pending litigation or other outstanding claims. These judgment and estimates are subject to change as new information becomes available.

Employee benefits

Depending on the laws and practices of the countries in which the Company operates, employees may be entitled to compensation when they retire or to a pension following their retirement. For state-managed plans and other defined contribution plans, the Company recognizes them as expenses when they become payable, with the Company's commitment being limited to our contributions.

The liability with respect to defined benefit plans is estimated using the following main assumptions:

- discount rate;
- future salary increases;
- employee turnover; and
- mortality tables.

The difference between the amount of the liability at the beginning of a fiscal year and at the close of that year is recognized through profit or loss for the portion representing the costs of services rendered and through other comprehensive income (loss) for the portion representing the actuarial gains and losses. Service costs are recognized in profit or loss and are allocated by function.

Actuarial gains and losses result from changes in actuarial assumptions and from differences between assumed and actual experience. Gains and losses recorded in other comprehensive income (loss) are amortized over expected remaining service periods to the extent they exceed 10% of the projected benefit obligation for the defined benefit plan.

The Company's payments for the defined-contribution plans are recognized as expenses in the Consolidated Statements of Operations and Comprehensive Loss for the period with which they are associated.

Income Tax

Income taxes are accounted for under the asset and liability method of accounting.

Deferred Taxes

Deferred taxes are recognized for the future tax consequences attributable to temporary differences between the financial reporting carrying amounts and tax bases of assets and liabilities, and on tax losses, using the liability method. Differences are defined as temporary when they are expected to reverse within a foreseeable future. The Company may only recognize deferred tax assets on net operating losses if, based on the projected taxable incomes within the next three years, management determines that it is probable that future taxable profit will be available against which the unused tax losses and tax credits can be utilized. As a result, the measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. If future taxable profits are considerably different from those forecasted that support recording deferred tax assets, the Company will have to revise downwards or upwards the amount of deferred tax assets, which would have a significant impact on the Company's financial results. Tax assets and liabilities are not discounted. Amounts recognized in the Consolidated Financial Statements are calculated at the level of each tax entity included in the consolidation scope. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

Uncertain tax position

Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

Income Tax Disclosures

In December 2023, the FASB issued ASU 2023 09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which enhances transparency by requiring additional disclosures related to income taxes. The amendments primarily require:

- A tabular reconciliation of the effective tax rate to the statutory rate, including both dollar amounts and percentages, with separate disclosure of items that are equal to or greater than 5% of the statutory rate.
- Disaggregation of income taxes paid between federal, state, and foreign jurisdictions, and identification of any individual jurisdiction that accounts for 5% or more of total income taxes paid.

The Company applied the ASU retrospectively by providing the revised disclosures for the year ended December 31, 2024.

As a French listed company, DBV determined its statutory tax rate based on its country of domicile, France [Domestic], which has a corporate income tax rate of 25%. In accordance with the income tax rate reconciliation and disaggregation requirements of ASU 2023-09, the Company evaluates income taxes paid by jurisdiction rather than solely by domicile.

Pursuant to the Company's transfer pricing arrangements, DBV incurred and paid U.S. income taxes representing 100% of total income taxes paid for fiscal year 2024. Accordingly, the United States is presented as a separate significant jurisdiction. Income taxes paid in other foreign jurisdictions are aggregated within the "Foreign" category, with Australia comprising the remaining foreign taxes paid.

Segment Information

The Company operates in a single operating segment: the conducting of research and development of epicutaneous immunotherapy products in order to market them in the future. The assets, liabilities, and operating losses recognized are primarily located in France.

Other Items in the Comprehensive Loss

Comprehensive loss is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), such as foreign currency translation adjustments. These changes in equity are presented net of tax.

Net Loss Per Share

The Company calculates basic and diluted net loss per ordinary share by dividing the net loss by the weighted-average number of ordinary shares outstanding during the period. For the years ended December 31, 2025 and 2024, the Company has excluded the effects of all potentially dilutive shares, which include outstanding ordinary stock options, warrants to purchase ordinary shares, and restricted stock units, from the weighted-average number of ordinary shares outstanding as their inclusion in the computation for these years would be anti-dilutive due to net losses incurred.

Subsequent Events

The Consolidated Statements of Financial Position and the Consolidated Statements of Operations and Comprehensive Loss of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that existed as of the end of the period covered. The Company has evaluated subsequent events from the balance sheet date through the issuance date of this report.

Note 2 Significant Events and Transactions of the Period

March 2025 PIPE Financing

The Company raised proceeds in the 2025 PIPE consisting of i) a share capital increase without preferential subscription rights reserved to categories of persons satisfying determined characteristics pursuant to the 24th resolution of the 2024 General Meeting completed on April 7 2025, for an amount of €38 million ($41 million), consisting of the issuance of (i) 34,090,004 new shares at a par value of €0.10 (the "New Shares") each with warrants of the Company attached (the "ABSA Warrants", and together with the New Shares, the "ABSA") at a subscription price of €1.1136 per ABSA and (ii) up to 59,657,507 additional new shares, if all the ABSA Warrants attached to the New Shares are exercised (the "ABSA Warrant Shares"); and ii) the issue through an offering reserved to categories of persons satisfying determined characteristics of 71,005,656 units (the "PFW-BS-PFW") completed on April 7, 2025 for an amount of €79 million ($85 million) at a subscription price of €1.1136 per PFW-BS-PFW (of which €1.1036 will have been prefunded on the issue date), each PFW-BS-PFW consisting of one pre-funded warrant to subscribe for one share of the Company (the "First Pre-Funded Warrants") and one warrant (the "BS Warrants") to subscribe to one second pre-funded warrants (the "Second Pre-Funded Warrants"), each of which entitles the holder to subscribe for 1.75 shares of the Company (the "Second PFW Shares"), allowing to issue up to 71,005,656 additional new shares if all the First Pre-Funded Warrants are exercised (the "First PFW Shares") and up to 124,259,898 additional new shares if all the Second Pre-Funded Warrants are exercised (the "Second PFW Shares", together with the ABSA Warrant Shares and the First Pre-Funded Warrant Shares, the "Warrant Shares", and together with the New Shares, the "Offered Shares"). The Company received initial gross proceeds of $125.5 million (€116.3 million) on April 7, 2025.

On January 16, 2026, the Company announced additional gross proceeds of $195.0 million (€166.7 million at the exchange rate of 1 EUR = $1.17) resulting from the full exercise of the ABSA Warrants and BS Warrants, following the announcement of the positive VITESSE Topline Results on December 16, 2025. Of these proceeds, $100.7 million in gross proceeds (€85.7 million, at the exchange rate of 1 EUR = $1.17) was received as of December 31, 2025, with the remaining amount received in January 2026.

The Accounting treatment is detailed into **Note 1 Nature of the business and principles and accounting methods, Significant contracts**.

At-The-Market ("ATM") equity program offering

In September 2025, the Company entered into a Sales Agreement (the "Sales Agreement") with Citizens JMP Securities, LLC ("Citizens"), with respect to an equity offering program (the "ATM Offering") pursuant to which the Company may offer and sell ADSs, from time to time, through Citizens as its sales agent. Pursuant to the Sales Agreement and a prospectus supplement the Company has filed related to the ATM Offering, the Company may offer and sell ADSs having an aggregate offering price of up to $150.0 million from time to time through Citizens. The issuance and sale, if any, of the ADSs by the Company under the Sales Agreement will be made pursuant to the Company's previously filed and effective registration statement on Form S-3 (Registration Statement No. 333-271166). Sales of the Company's ADSs, if any, in the ATM Offering may be made in sales deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act from time to time. Pursuant to the ATM Offering, the Company received (i) a total gross amount of $30 million from the sale of 11,538,460 Ordinary Shares (underlying 2,307,692 ADSs) on October 6, 2025, (ii) a total gross amount of $30 million from the sale of 10,714,300 Ordinary Shares (underlying 2,142,860 ADSs) on October 29, 2025, and (iii) a total gross amount of $5 million from the sale of 1,700,000 Ordinary Shares (underlying 340,000 ADSs) on November 19, 2025.

The Company entered into a Manufacturing & Supply Agreement with SANOFI on August 29, 2025

On August 29, 2025, the Company entered into a Supply Agreement with SANOFI under which SANOFI will manufacture and supply the Viaskin Peanut API for the Company during the agreement term. The Agreement has an initial term of 4 years with a possibility to extend for an additional period. The effective date is January 1, 2025. This Agreement includes terms related to manufacturing, quality control, pricing, volume commitments, and supply obligations. The Agreement is designed to support commercial-scale API manufacturing capacity in preparation for a potential BLA submission and subsequently, the commercial launch of the Viaskin Peanut patch in the United States, if approved.

The Company has non-cancellable minimum commitments for products and services under the Supply Agreement. Under US GAAP, take-or-pay arrangements are generally considered firm purchase commitments. As of December 31, 2025, the Company has assessed its ability to meet the obligations as per U.S. GAAP requirements (ASC 440-10: Commitments, ASC 450-20: Loss Contingencies and ASC 330-10-35: Inventory and purchase commitments) and confirm to commit to agreed volumes. Hence, we have not recognized on the balance sheet any loss provision.

The Company expects to incur expenditures related to support for BLA and PAI preparation, cold storage rental, over the Supply Agreement term. These expenditures are consistent with the Company's planned investments to strengthen its supply chain readiness ahead of potential regulatory milestones.

Implementation of a foreign exchange SWAP (Non-qualified derivative instrument)

DBV Technologies S.A. entered on December 30, 2025, into a foreign currency swap with Société Générale to reduce the exposure to US dollar related to the operations with DBV Technologies Inc. in the United States.

This instrument is based on a notional amount corresponding to the month-end treasury current account balance, valued at the spot rate on the transaction date, with a maturity running until the end of the following month to hedge the subsidiary's immediate operating needs, it can be completed by additional comparable derivatives in order to hedge additional needs. As of December 31, 2025, the notional amount is $1.8 million with an initial spot rate of 1.1765, with a rate of 1.1790 with a maturity January 30, 2026. The "mark-to-market" valuation of the instrument as of December 31, 2025, is $(5) thousands.

Legal Proceedings

From time to time, we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently subject to any material legal proceedings.

Note 3 Cash and Cash Equivalents

The following table presents for each reported period, the breakdown of cash and cash equivalents:

	December 31,	
	2025	**2024**
Cash	127,118	32,456
Cash equivalents	67,050	—
Total cash and cash equivalents as reported in the statements of financial position	**194,167**	**32,456**

Cash equivalents are convertible into cash at no or insignificant cost on demand within 32 days or less. They are measured using Level 1 fair value measurements.

Note 4 Other Current Assets

Other current assets consisted of the following:

	December 31,	
	2025	**2024**
Research tax credit	5,860	3,980
VAT Assets	8,711	4,452
Prepaid expenses	2,628	1,541
Other receivables	1,577	1,959
Total	**18,776**	**11,932**

The other tax claims are primarily related to deductible VAT. Prepaid expenses are comprised primarily of finance, legal as well as scientific consulting fees and insurance expenses. Prepaid expenses also include upfront payments which are recognized over the term of the ongoing clinical studies.

Research tax credit

In the fiscal year ended December 31, 2021, the Company recovered its Small & Medium Enterprise “SME” status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit.

During the year ended December 31, 2025, the Company received the reimbursement of 2024 fiscal year research tax credit for a total amount of $4.3 million.

The variance in Research Tax Credit disclosed is detailed below:

	Amount in thousands of US Dollars
Opening research tax credit receivable as of January 1, 2024	**8,857**
+ Other operating income	**4,146**
- Payment received	**(8,676)**
- Adjustment and currency translation effect	**(348)**
Opening research tax credit receivable as of January 1, 2025	**3,980**
+ Other operating income	5,636
- Payment received	(4,328)
- Adjustment and currency translation effect	573
Closing research tax credit receivable as of December 31, 2025	**5,860**
Of which - Non-current portion	—
Of which - Current portion	*5,860*

Note 5 Property, Plant, and Equipment

Property and equipment, net consisted of the following:

	01/01/2024	Currency translation effect	Increase	Decrease	Reclassification	31/12/2024
Laboratory equipment	24,839	(1,501)	—	—	388	23,726
Fixture and installations	3,327	(116)	30	(3,042)	1,113	1,312
Computer equipment	1,977	(87)	1	—	(101)	1,790
Other property, plant and equipment	—	(42)	—	(7)	871	822
Property, plant, and equipment in progress	1,433	(77)	2,101	—	(2,271)	1,185
Total, gross	**31,576**	**(1,825)**	**2,132**	**(3,049)**	**—**	**28,834**
Accumulated depreciation of laboratory equipment	(13,539)	901	(2,274)	—	—	(14,912)
Accumulated depreciation of fixtures and installations	(2,933)	63	(271)	3,042	—	(99)
Accumulated depreciation of computer equipment	(1,262)	68	(152)	—	—	(1,346)
Accumulated depreciation of other property, plant and equipment	(1,219)	66	(24)	6	—	(1,171)
Less accumulated amortization and depreciation	(18,954)	1,098	(2,721)	3,049	—	(17,528)
Total, net	**12,622**	**(726)**	**(589)**	**—**	**—**	**11,306**

	01/01/2025	Currency translation effect	Increase	Decrease	Reclassification	12/31/2025
Laboratory equipment	23,726	3,139	—	—	783	27,648
Fixture and installations	1,312	168	—	—	—	1,480
Computer equipment	1,790	196	15	—	48	2,048
Other property, plant and equipment	822	91	1	—	1	914
Property, plant, and equipment in progress	1,185	145	667	(11)	(831)	1,156
Total, gross	**28,834**	**3,740**	**683**	**(11)**	**—**	**33,245**
Accumulated depreciation of laboratory equipment	(14,912)	(2,059)	(2,654)	—	—	(19,625)
Accumulated depreciation of fixtures and installations	(99)	(18)	(177)	—	—	(295)
Accumulated depreciation of computer equipment	(1,346)	(146)	(141)	—	—	(1,633)
Accumulated depreciation of other property, plant and equipment	(1,171)	(137)	(15)	—	—	(1,323)
Less accumulated amortization and depreciation	(17,528)	(2,361)	(2,987)	—	—	(22,876)
Total, net	**11,306**	**1,379**	**(2,304)**	**(11)**	**—**	**10,370**

The depreciation and amortization expense for each of the years ended December 31, 2025 and 2024 was $3.0 million and $2.7 million respectively.

Note 6 Lease contracts

Future minimum lease payments under the Company's operating leases' right of use as of December 31, 2025 and 2024, are as follows:

(Amounts in thousands of US Dollars)	31/12/2025			31/12/2024		
	Real Estate	**Other assets**	**Total**	**Real Estate**	**Other assets**	**Total**
Current portion	1,335	77	1,412	810	26	836
Year 2	977	7	984	1,222	7	1,228
Year 3	977	7	984	1,230	7	1,237
Thereafter	4,247	2	4,248	5,127	9	5,136
Total minimum lease payments	**7,534**	**93**	**7,628**	**8,388**	**49**	**8,437**
Less: Effects of discounting	(1,098)	(5)	(1,102)	(1,463)	(23)	(1,486)
Present value of lease liabilities	**6,436**	**88**	**6,526**	**6,925**	**26**	**6,951**
Less: current portion	(1,043)	(74)	(1,117)	(648)	(6)	(654)
Long-term lease liabilities	**5,394**	**14**	**5,409**	**6,278**	**20**	**6,297**
Weighted average remaining lease term (years)	6.95	0.19		7.49	0.02	
Weighted average discount rate	**5.02 %**	**0.07 %**		**5.02 %**	**0.02 %**	

The Company recognizes rent expense, calculated as the remaining cost of the lease allocated over the remaining lease term on a straight-line basis. Rent expense presented in the consolidated statement of operations and comprehensive loss was:

(Amounts in thousands of US Dollars)	December 31,	
	2025	**2024**
Operating lease expense / (income)	1,214	1,868
Net termination impact	(90)	(52)

In November 2023, the Company signed agreements for the new headquarters in Châtillon, France:

- a short term lease agreement in order to fit the new offices;
- a lease agreement starting on April 16, 2024.

The lease commencement was based upon delivery of possession of the premises by the Landlord and occurred in November 2023. Right of use and related lease debt have been recorded starting November 2023 for a gross amount of $4.5 million.

Pursuant section 8 of the Sublease between DBV Technologies, Inc. and Envision Pharma Inc. for Premises located at 10 Independence Boulevard, Warren, New Jersey ("Sublease"), Envision Pharma Inc. gave notice of its intention to terminate the Sublease as of December 30, 2026. The Company adjusted accordingly the Right of Use asset and the lease liability and reclassed the remaining liability onto current liabilities.

Supplemental cash flow information related to operating leases is as follows for the year ended December 31, 2025 and 2024:

(Amounts in thousands of US Dollars)	December 31,	
	2025	**2024**
Cash paid for amounts included in the measurement of lease liabilities	—	—
Operating cash flows from operating leases	563	1,053

Note 7 Other non-current assets

Other non-current assets consisted of the following:

	December 31,	
	2025	**2024**
Deposits, pledged securities and other non-current financial assets	5,189	4,312
Liquidity contract	620	111
Total non-current assets	**5,809**	**4,423**

The other non-current assets are composed of Fareva La Vallée prepaid Right of Use, security deposits paid to premises lessors, pledged securities and the liquidity contract.

As per the Company liquidity contract, 74,580 treasury shares were allocated as a reduction of Shareholders' Equity as of December 31, 2025, the cash balance being maintained in financial assets.

Note 8 Trade payables and Other Current Liabilities

Trade Payables

No discounting was performed on the trade payables to the extent that the amounts did not present payment terms longer than one year at the end of each fiscal year presented.

Other Current Liabilities

Other current liabilities consisted of the following:

	December 31,	
	2025	**2024**
Social debt	13,689	7,294
Tax liabilities	592	188
Other debts	1,468	846
Total	**15,750**	**8,328**

The increase in social debt compared to the prior period primarily reflects (i) the expansion of the Company's teams, resulting in higher payroll-related liabilities, (ii) higher bonus accruals recognized in line with performance and headcount growth, and (iii) the corresponding increase in social security and payroll tax contributions associated with these accruals.

Due dates of liabilities

The following table shows the maturity of the Company's liabilities (except leases disclosed in "Note 6 - Lease contract"):

	Amount	**2025**	**2026**	**2027**	**2028**	Thereafter
Other liabilities	15,750	15,750	—	—	—	—
Supplier accounts payable and related payables	40,941	40,941	—	—	—	—
Total Liabilities	**56,691**	**56,691**	**—**	**—**	**—**	**—**

Note 9 Fair Value Measurement

The Company reports assets and liabilities recorded at fair value on the Company's consolidated balance sheets based upon the level of judgment associated with inputs used to measure their fair value.

The fair value measurement level within the fair value hierarchy for a particular asset or liability is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial instruments not measured at fair value on the Company's consolidated statement of financial position, but which require disclosure of their fair values include cash and cash equivalents, deposits, liquidity contract, accounts payable, and conditional advances. The fair values of these financial instruments are deemed to approximate their carrying amount.

There has been no transfer between levels of the fair value hierarchy during the years ended December 31, 2024 and 2025.

The financial instruments recognized on the balance sheet are analyzed as follows as of December 31, 2024 :

	Breakdown by financial instrument class - balance sheet value					*Level of fair value*		
2024 (in thousands of dollars)	**Carrying value**	**Fair value through P&L**	**Assets at amortized cost**	**Liabilities at amortized cost**	**Derivative financial instrument**	**Level 1**	**Level 2**	**Level 3**
Deposits	4,312	—	4,312	—	—		—	—
Liquidity contract	111	111	—	—	—	111	—	—
Accounts receivable	680	—	680	—	—	—	—	—
Cash and cash equivalents	32,456	32,456	—	—	—	32,456	—	—
Total Assets	**37,559**	**32,567**	**4,992**	**—**	**—**	**32,567**	**—**	**—**
Other liabilities	8,328	0	0	8,328	0	0	0	0
Accounts payables	22,032	0	0	22,032	0	0	0	0
Total Liabilities	**30,360**	**—**	**—**	**—**	**30,360**	**—**	**—**	**—**	**—**	**—**

The financial instruments recognized on the balance sheet are analyzed as follows as of December 31, 2025 :

	Breakdown by financial instrument class - balance sheet value					*Level of fair value*		
	Carrying value	**Fair value through P&L**	**Assets at amortized cost**	**Liabilities at amortized cost**	**Derivative financial instrument**	**Level 1**	**Level 2**	**Level 3**
Deposits	5,189	0	5,189	0	0	0	0	0
Liquidity contract	620	620	0	0	0	620	0	0
Cash and cash equivalents	194,167	194,167	0	0	0	194,167	0	0
Total Assets	**199,977**	**194,788**	**5,189**	**—**	**—**	**194,788**	**—**	**—**
Other liabilities	15,750	5	0	15,750	5	5	0	0
Accounts payables	40,941	0	0	40,941	0	0	0	0
Total Liabilities	**56,691**	**5**	**—**	**56,691**	**5**	**5**	**—**	**—**

Financial instruments evolved during the year primarily as a result of the financings conducted resulting in a significant increase in cash and cash equivalents .

Derivative Instruments

The Company is exposed to increasing foreign exchange risk due to a portion of its procurement activities being conducted in the United States and invoiced in U.S. dollars, as well as the activity of its subsidiary DBV Technologies Inc., in connection with the Company's preparation for the potential launch of the VIASKIN Peanut patch in the United States, if approved.

This exposure has been increased by the continued depreciation of the U.S. dollar observed over the past year, which increases volatility and uncertainty regarding foreign-currency-denominated operating costs.

In this context, since 2025, the Company has hedged the current account of its US subsidiary through the use of financial instruments (foreign exchange swaps entered into with banking counterparties), which are linked to the subsidiary's current account as of December 31, 2025.

The Company's policy is not to enter into derivative transactions for speculative purposes.

		As of December 31, 2025				
			Fair value		**Due date**	
(In Million of dollars)		**Notional amount**	Asset	Liabilities	<1 year	1 – 5 years	>5 years
Foreign exchange SWAP Forward sale at maturity	Non-qualified derivative	1,800		—	1,800		

The impact of financial instruments not qualifying for hedge accounting of future cash flows is included in "Foreign exchange gains/(losses) (excluding operating activities)" within financial result ($(5) thousand as of December 31, 2025). The Company did not hold any derivative instruments in 2024.

Note 10 Share Capital Issued

The share capital, as of December 31, 2025, is set at the sum of $26,911,786.4 (€23,567,086.40). It is divided into 235,670,864 fully authorized, subscribed and paid-up shares with a nominal value of €0.10.

The 2024 General Meeting held on June 11, 2025, duly convened and validly deliberating under the quorum and majority conditions applicable to ordinary general meetings, having reviewed the report of the Board of Directors, resolved to allocate the entire loss for the financial year ended December 31, 2024, amounting $(40,192,552.87) (€35,154,861.25) against the share premium account (Allocation of accumulated net losses).

The General Meeting held on May 16, 2024, duly convened and validly deliberating under the quorum and majority conditions applicable to ordinary general meetings, having reviewed the report of the Board of Directors, resolved to allocate the entire loss for the financial year ended December 31, 2023, amounting to $66,432,799.17 (€61,327,401.00), to the debit balance of retained earnings (accumulated deficit). The General Meeting also resolved to offset the same amount against the share premium account (Allocation of accumulated net losses).

With respect to the 2025 PIPE financing, the transaction and its accounting treatment are described into **Note 1 Nature of the business and principles and accounting methods, Significant contracts.**

The 2022 Warrants were classified as a component of permanent equity because they were freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the 2022 Warrants did not provide any guarantee of value or return. Accordingly, the pre-funded warrants were classified as equity and accounted for as a component of additional paid-in capital at the time of issuance.

The table below presents the changes in the share capital of the Company as of December 31, 2024 and 2025 at historical rate:

Amounts in thousands of U.S. Dollars except share and per share data

Date	Nature of the transactions	Share capital in USD*	Additional paid-in capital	Number of shares
	Balance as of January 1, 2024	**10,972,101**	**377,468**	**96,431,770**
03/23/2024	Capital increase by employee warrants	275	—	2,599
05/12/2024	Capital increase by employee warrants	169	—	1,600
05/16/2024	Retained earnings charged on share premium	0	(66,433)	0
05/19/2024	Capital increase by employee warrants	264	—	2,500
05/22/2024	Capital increase by employee warrants	2,339	(2)	22,112
05/24/2024	Capital increase by employee warrants	3,437	(3)	32,497
07/29/2024	Capital increase by employee warrants	619	(1)	5,849
09/23/2024	Capital increase by employee warrants	275	—	2,599
11/15/2024	Capital increase by share warrants	635,692	—	6,010,000
11/18/2024	Capital increase by employee warrants	42	—	400
11/19/2024	Capital increase by employee warrants	264	—	2,500
11/20/2024	Capital increase by employee warrants	10,306	(10)	97,436
11/21/2024	Capital increase by employee warrants	17,651	(18)	166,874
11/22/2024	Capital increase by employee warrants	2,319	(2)	21,925
11/24/2024	Capital increase by employee warrants	4,954	(5)	46,840
	Balance as of December 31, 2024	**11,650,708**	**310,993**	**102,847,501**
12/31/2024	Share base payment accrual		4,620	
	Total Equity RFW as of December 31, 2024	**11,650,708**	**315,613**	**102,847,501**
01/09/2025	Capital increase by employee warrants	839	(1)	7,300
01/29/2025	Capital increase by employee warrants	168	—	1,462
03/23/2025	Capital increase by employee warrants	299	—	2,605
04/07/2025	Capital increase by ordinary shares	3,916,856	27,386	34,090,004
05/12/2025	Capital increase by employee warrants	46	—	400
05/19/2025	Capital increase by employee warrants	287	—	2,500
05/22/2025	Capital increase by employee warrants	2,519	(3)	21,925
06/11/2025	Retained earnings charged on share premium	0	(40,193)	0
07/29/2025	Capital increase by employee warrants	168	—	1,462
10/08/2025	Capital increase by ordinary shares	1,325,740	26,995	11,538,460
10/28/2025	Capital increase by ordinary shares	654,916	27,557	5,700,000
10/27/2025	Capital increase by ordinary shares	1,711,973	10,776	14,900,000
10/31/2025	Capital increase by ordinary shares	1,231,046	27,556	10,714,300
11/05/2025	Capital increase by ordinary shares	1,161,474	9,402	10,108,780
11/07/2025	Capital increase by ordinary shares	206,816	1,674	1,800,000
11/12/2025	Capital increase by employee warrants	46	—	400
11/17/2025	Capital increase by ordinary shares	114,898	723	1,000,000
11/20/2025	Capital increase by employee warrants	31,841	(32)	277,128
11/21/2025	Capital increase by ordinary shares	195,326	4,454	1,700,000
11/21/2025	Capital increase by employee warrants	24,661	(25)	214,637
11/22/2025	Capital increase by employee warrants	2,367	(2)	20,605
12/02/2025	Capital increase by ordinary shares	669,651	4,826	5,828,249
01/08/2026	Capital increase by ordinary shares (1)	396,396	16,679	3,450,000
01/07/2026	Capital increase by employee Stock Option (1)	1,525	32	13,275
12/23/2025	Capital increase by ordinary shares	1,060,151	7,639	9,226,931
12/23/2025	Capital increase by ordinary shares	570,140	3,589	4,962,164
12/23/2025	Capital increase by ordinary shares	1,060,151	7,639	9,226,931
12/23/2025	Capital increase by ordinary shares	167,413	1,206	1,457,064
12/29/2025	Capital increase by ordinary shares	753,358	5,429	6,556,781
	Balance as of December 31, 2025	**26,911,786**	**465,811**	**235,670,864**
12/31/2025	Share base payment accrual		5,387	
	Issuance of warrants		70,053	
	Total Equity RFW as of December 31, 2025	**26,911,786**	**541,251**	**235,670,864**

(1) The dates on which capital increases are recognized do not follow a strictly chronological order, as certain transactions were recorded retrospectively in order to reflect adjustments resulting from the exercise of financial instruments and financing transactions that occurred previously.

(2) Share premiums are presented and accounted for in accordance with the terms described in Note 1 - Share Capital

Note 11 Share-Based Payments

The Board of Directors has been authorized by the General Meeting of the Shareholders to grant RUSs, SOs, and BSAs for the last three years, as follows:

Share-based payments instrument	General meeting of shareholders	Board of directors meeting	Grant date	Number granted
AGA	12/4/2023	1/9/2023	1/9/2023	35,800
SO	12/4/2023	1/9/2023	1/9/2023	59,200
AGA	12/4/2023	11/20/2023	11/20/2023	912,650
SO	12/4/2023	11/20/2023	11/20/2023	2,290,722
AGA	12/4/2023	1/16/2024	1/16/2024	59,000
SO	12/4/2023	1/16/2024	1/16/2024	262,000
AGA	5/16/2024	5/16/2024	5/16/2024	65,000
SO	5/16/2024	5/16/2024	5/16/2024	272,000
AGA	5/16/2024	11/21/2024	11/21/2024	1,181,700
SO	5/16/2024	11/21/2024	11/21/2024	2,267,300
SO	5/16/2024	12/4/2024	12/4/2024	813,200
AGA	11/6/2025	6/23/2025	6/23/2025	35,000
SO	11/6/2025	6/23/2025	6/23/2025	215,000
AGA	11/6/2025	11/21/2025	11/21/2025	1,470,600
SO	11/6/2025	11/21/2025	11/21/2025	4,091,150

In the following tables related to share-based payments, exercise prices, grant date share fair values and fair value per equity instruments are provided in euros, as the Company is incorporated in France and the euro is the currency used for the grants.

11.1 Non-employee warrants

The Company’s board of directors has been authorized by the shareholders’ general meeting to grant BSAs to non-employee’s members of the Board of Directors and members of the Scientific Advisory Board.

The BSAs plans granted by the Board of Directors until 2018 are similar in their nature and conditions, except for the exercise price that is comprised between €37.24 and €69.75.

During the year ended December 31, 2021, pursuant to the authorization granted by the General Meeting of the Shareholders held on May 19, 2021, the Company offered the directors the opportunity to subscribe for warrants to purchase ordinary shares on May 19, 2021 and on June 3, 2021, the directors subscribed for warrants to purchase an aggregate of 39,185 ordinary shares. These warrants have a contractual life of 4 years from their date of issuance and are not subject to a performance condition. Unless otherwise decided by the Board of Directors, these warrants may be exercised at any time prior to their expiration, provided that the beneficiary still holds a seat on the Board of Directors at the time of exercise, and subject to applicable French laws and regulations applicable to companies whose securities are listed on a regulated stock market. The fair value of the warrants has been estimated using the Cox-Ross Rubinstein binomial option pricing model.

Warrant fair value assumptions are:

Weighted average share price at grant date (in €)	10.75
Weighted average expected volatility	90.0 %
Weighted average risk-free interest rate	(0.53)%
Weighted average expected term (in years)	3.21
Dividend yield	—
Weighted average fair value of warrants (in €)	0.57

The Company no longer grants neither BSA or BSPCE to non-employee members of the Board of Directors or to members of the Scientific Advisory Board.

The following table summarizes all BSA warrants activity during the year ended December 31, 2024:

	Number of warrants outstanding	Weighted- average exercise price (in Euros)	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value (in thousands of Euros)
Balance as of December 31, 2023	**244,693**	**49.43**	**3.47**	**—**
Expired during the period			—	—
Balance as of December 31, 2024	**244,693**	**49.43**	**2.47**	**—**
Warrants exercisable as of December 31, 2024	*244,693*	*49.43*		—

The following table summarizes all BSA activity during the year ended December 31, 2025:

	Number of warrants outstanding	Weighted- average exercise price (in Euros)	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value (in thousands of Euros)
Balance as of December 31, 2024	**244,693**	**49.43**	**2.47**	**—**
Expired during the period	(137,685)		—	—
Balance as of December 31, 2025	**107,008**	**52.35**	**1.50**	**—**
Warrants exercisable as of December 31, 2025	*107,008*	*52.35*		—

11.2 Stock options

The Company's Board of Directors has been authorized by the shareholders' general meeting to grant SO to employees.

The different stock options plans granted by the Board of Directors are similar in their nature and conditions, except for the exercise price that is comprised between €0.71 and €74.22.

All SO issued have a ten-year contractual life. SO are expensed in accordance with the following vesting conditions:

- Before June 22, 2018 and from January 15, 2020 to July 29, 2022, SO granted mainly vest over four years at a rate of 25% upon the first anniversary of the issuance date and 12.5% every six months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions).
- Between June 22, 2018 and January 15, 2020, SO may be exercised by the beneficiary once both of the following conditions have been met:
  - service condition: 25% upon the first anniversary of the issuance date and 12.5% every six months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions); and
  - performance condition: approval of Viaskin™ Peanut by the US Food and Drug Administration.
- Since November 21, 2022, SO granted mainly vest over four years at a rate of 25% upon the first anniversary of the issuance date and 25% every 12 months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions).

Performance conditions which are other than market conditions, are taken into account by adjusting the number of equity instruments included in the measurement of the transaction amount but are not taken into account when estimating the fair value of the shares. Estimated achievement of performance conditions is reviewed at each reporting date.

The Company also applied a forfeiture rate for each grant according to its respective characteristics and composition. This forfeiture rate is reviewed at each reporting date.

The following table summarizes all stock options activity during the year ended December 31, 2024:

	Number of SO outstanding	Weighted- average exercise price (in Euros)	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value (in thousands of Euros)
Balance as of December 31, 2023	**7,137,641**	**8.49**	**8.18**	**—**
Granted during the period	3,614,500	0.86	—	—
Forfeited during the period	(283,938)	5.98	—	—
Exercised during the period	—	—	—	—
Expired during the period	(15,300)	—	—	—
Balance as of December 31, 2024	**10,452,903**	**5.93**	**7.96**	**—**
Options exercisable as of December 31, 2024	2,065,595	21.02	4.40	—

The following table summarizes all stock options activity during the year ended December 31, 2025:

	Number of SO outstanding	Weighted- average exercise price (in Euros)	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value (in thousands of Euros)
Balance as of December 31, 2024	**10,452,903**	**5.93**	**7.96**	**—**
Granted during the period	4,306,150	2.47	—	—
Forfeited during the period	(486,300)	2.32	—	—
Delivered during the period	(40,075)	4.99	—	—
Expired during the period	(128,100)	—	—	—
Balance as of December 31,2025	**14,104,578**	**4.64**	**7.89**	**—**
Options exercisable as of December 31, 2025	2,751,695	6.18	4.31	2,766,171

The expense recognized into the Consolidated statements of operations is $4.1 millions dollars as of December 31, 2025, against $3.3 million as of December 31, 2024.

Fair value of stock options

Determining the fair value of the share-based payments at the grant date requires judgment. The Company calculated the fair value of stock options instruments on the grant date using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly subjective assumptions, including the expected volatility, expected term, risk-free interest rate and dividend yield.

Exercise price

The exercise price of the Company's stock awards is based on the fair market value of our ordinary shares.

Risk-free interest rate

The risk-free interest rate is based on French government bonds (GFRN) with a maturity corresponding to the stock options maturity.

Expected term

The Company determines the expected term based on the average period the stock options are expected to remain outstanding.

Expected Volatility

The Company determines the expected volatility based on the historical data period corresponding to the stock options expected maturity.

Expected Dividend yield

The Company has never declared or paid any cash dividends, and it does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero.

The Company estimated the following assumptions for the calculation of the fair value of the stock options:

Stock options per grant date	2025	2024
Weighted average shares price at grant date in €	2.39	0.76
Weighted average expected volatility	86.63 %	90.61 %
Weighted average risk-free interest rate	2.91 %	2.58 %
Weighted average expected term (in years)	6.25	6.25
Weighted average fair value of stock-options in €	1.73	0.57

11.3 Restricted stock units

The Company's board of directors has been authorized by the shareholders' general meeting to grant RSUs to employees.

RSUs are measured based on the fair market value of the underlying stock on the date of grant and recognized as an expense on a straight-line basis in accordance with the following vesting conditions:

- Before May 31, 2019, the vesting of RSUs granted is subject to the expiration of the presence condition of one (1) or two (2) years (except in specific board of directors' decisions). The release of RSUs for these plans is subject to the achievement of performance conditions (submission of a BLA to U.S. FDA for VIASKIN® Peanut, approval of VIASKIN® Peanut by the U.S. FDA, first sale of VIASKIN® Peanut in the United States).
- Between May 31, 2019 and November 23, 2020, the vesting of RSUs is subject either to the expiration of the presence condition of two (2) years only, or to the dual condition of expiration of the presence condition and achievement of the performance condition (date of approval of VIASKIN® Peanut by the U.S. FDA).
- Between November 24, 2020 and July 29, 2022, RSUs vest over four years at a rate of 25% upon the first anniversary of the issuance date and 12.5% every six months thereafter, subject to the beneficiary being still employed by the Company (except in specific board of directors' decisions).
- Since November 21, 2022, RSUs vest over four years at a rate of 25% upon the first anniversary of the issuance date and 25% every 12 months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions).
-

Performance conditions, which are other than market conditions, are taken into account by adjusting the number of equity instruments included in the measurement of the transaction amount but are not taken into account when estimating the fair value of the shares. Estimated achievement of performance conditions is reviewed at each reporting date.

RSU plans may be subject to a conservation period under French governing laws.

The Company applied a forfeiture rate for each grant according to its respective characteristics and composition. This forfeiture rate is reviewed at each reporting date.

The following table summarizes all RSUs activity for the year ended December 31, 2024:

	Number of RSU outstanding	Weighted- average grant date fair value in Euros
Balance as of December 31, 2023	**2,021,370**	**11.03**
Granted during the period	1,305,700	0.60
Forfeited during the period	(174,278)	2.29
Released during the period	(339,426)	3.22
Balance as of December 31, 2024	**2,813,366**	**7.67**

The following table summarizes all RSUs activity for the year ended December 31, 2025:

	Number of RSU outstanding	Weighted- average grant date fair value in Euros
Balance as of December 31, 2024	**2,813,366**	**7.67**
Granted during the period	1,505,600	2.37
Forfeited during the period	32,380	5.53
Released during the period	(742,999)	1.87
Balance as of December 31, 2025	**3,608,347**	**6.61**

The expense recognized into the Consolidated statements of operations is stable at $1.3 millions dollars as of December 31, 2025 and as of December 31, 2024. The forfeited bucket includes contingent stock options.

11.4 Reconciliation of the share-based payment expenses with the Consolidated Statements of Operations and Comprehensive Loss

		December 31,	
		2025	2024
Research & development	SO	(1,433)	(1,431)
	RSU	(828)	(913)
Sales & marketing	SO	(78)	(80)
	RSU	(36)	(35)
General & administrative	SO	(2,556)	(1,794)
	RSU	(456)	(367)
Total share-based compensation (expense)		**(5,387)**	**(4,620)**

Note 12 Contingencies & Employee Benefits

Non-current contingencies and current contingencies break down as follows:

	December 31,	
	2025	2024
Current contingencies	217	122
Non-current contingencies	1,513	838
Total contingencies	**1,730**	**961**

The table below shows movements in contingencies:

	Pension retirement obligations	Other contingencies	Total
At January 1, 2024	**935**	**3,958**	**4,894**
Increases in liabilities	88	125	212
Used liabilities	—	(3,877)	(3,877)
Actuarial gains and losses on defined-benefit plans	(163)	—	(163)
Currency translation effect	(22)	(84)	(105)
At January 1, 2025	**838**	**122**	**961**
Increases in liabilities	105	81	186
Actuarial gains and losses on defined-benefit plans	408	—	408
Currency translation effect	162	14	176
At December 31, 2025	**1,513**	**217**	**1,730**
Of which current	—	217	217
Of which non-current	1,513	—	1,513
Life table	TGH05-TGF05		
Collective agreement	National Collective Agreement of the pharmaceutical industry ;		

The Company does not hold any plan assets for any of the periods presented.

As part of the estimation of the retirement commitments, the following assumptions were used for all categories of employees:

	December 31,	
	2025	2024
% Social security contributions	50.0 %	50.0 %
Salary increases	3.5 %	2.0 %
Discount rate—Iboxx Corporates AA 10+	3.96 %	3.38 %
Expected staff turnover	12.5 %	10.0 %
Estimated retirement age	67	67
Life table	TGH05-TGF05	
Collective agreement	National Collective Agreement of the pharmaceutical industry	

Note 13 Operating Income

The operating income is broken down in the following manner:

	December 31,	
	2025	2024
Research tax credit	5,636	4,146
Other operating income	—	5
Total	**5,636**	**4,151**

We generated an operating income of $5.6 million for the year ended December 31, 2025 compared to $4.2 million for the year ended December 31, 2024. This increase reflects higher eligible activities performed during the period.

Note 14 Operating expenses and Allocation of Personnel Expenses

Operating expenses

Research and Development Expenses

The following table summarizes our research and development expenses for the years reported:

	December 31,			
	2025	2024	$ change	% of change
Research and Development expenses				
External clinical-related expenses	67,949	61,060	6,890	11%
Employee-related costs	20,522	17,213	3,309	19%
Share-based payment expenses	2,261	2,343	(82)	(4)%
Depreciation, amortization and other costs	9,889	7,338	2,551	35%
Pre-Commercial Inventory	16,062	1,388	14,674	1057%
Total Research and Development expenses	**116,682**	**89,342**	**27,341**	**31%**

Research and Development expenses increased by $27.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Pre-Commercial Inventory of $16.1 million reflects inventory build-up inception in anticipation of potential FDA approval.

External clinical-related expenses increased by $6.9 million, due to higher clinical trial activity driven by the initiation of patient recruitment for the COMFORT Toddlers study. This increase was partially offset by (1) lower spend compared to 2024 on the VITESSE Study following completion of final patient visits in 2025 and (2) from other studies that are completed or nearing completion.

Employee-related costs, excluding share-based payments, increased by $3.3 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily driven by full-time employees (“FTE”) growth. This increase reflects the full-year impact in 2025 of hires made in 2024, combined with additional recruitments in 2025. These hires were mainly in Medical Affairs, Quality, and Regulatory functions, primarily based in the U.S., and were made to support BLA submission and Commercial readiness activities. The increase also includes certain one-off costs related to the strong operational execution delivered in 2025.

Depreciation and amortization increased by $2.6 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, consequently to an accrual reversal related to CRO activities in the prior year, having a positive impact on the income statement and offsets the recurring depreciation and amortization.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
Sales & Marketing expenses				
External professional services and other costs	1,967	1,770	197	11 %
Employee-related costs incl. share-based payment expenses	1,254	890	364	41 %
Total Sales & Marketing expenses	**3,222**	**2,659**	**561**	**21 %**

Sales and marketing expenses increased by $0.6 million or the year ended December 31, 2025 compared to the year ended December 31, 2024. This increase was primarily attributable to higher pre-commercialization costs and increased headcount to support commercial readiness for Viaskin Peanut in North America.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years presented:

	December 31,			
	2025	**2024**	**$ change**	**% of change**
General & Administrative expenses				
External professional services	9,072	10,052	(980)	(10)%
Employee-related costs	12,972	8,981	3,991	44 %
Share-based payment expenses	3,012	2,161	851	39 %
Depreciation, amortization and other costs	7,731	7,545	186	2 %
Total General & Administrative expenses	**32,788**	**28,739**	**4,049**	**14 %**

General and administrative expenses increased by $4.0 million for the year ended December 31, 2025, compared to the year ended December 31, 2024.

The increase was primarily attributable to higher Employee-related costs, excluding share-based payments, which increased by $4.0 million driven by growth in full-time employees. These hires were mainly in Human Resources, Information Solutions, Finance, and Legal and Compliance functions to support commercial readiness. The increase also includes certain one-off costs related to strong operational execution in 2025.

This increase was partially offset by a $1.0 million decrease in External professional services, primarily due to the absence of one-time costs incurred in the prior year related to office relocations in France and the U.S., and trademark and patent activities.

Allocation of Personnel Expenses by Function:
The Company had 125 full time employees for the year ended December 31, 2025, in comparison with 108 employees for the year ended December 31, 2024.

	December 31,	
	2025	**2024**
Research and development expenses	22,783	19,557
Sales and marketing expenses	1,254	890
General and administrative expenses	15,984	11,142
Total personnel expenses	**40,021**	**31,588**

Allocation of Personnel Expenses by Nature:

	December 31,	
	2025	**2024**
Wages and salaries	24,904	20,670
Social security contributions	9,625	5,272
Expenses for pension commitments	105	1,026
Share-based payments	5,387	4,620
Total personnel expenses	**40,021**	**31,588**

The increase in personnel expenses is primarily driven by full-time employees ("FTE") growth. This increase reflects the full-year impact in 2025 of hires made in 2024, combined with additional recruitments in 2025. These hires were mainly in Medical Affairs, Quality, Regulatory and G&A functions, primarily based in the U.S., and were made to support BLA submission and Commercial readiness. The increase also includes certain one-off costs related to strong execution in 2025.

Note 15 Income Tax & deferred Taxes

Reconciliation between the Effective and Nominal Income Tax Expense

As a French listed company, DBV determined its statutory tax rate based on its country of domicile, France [Domestic], which has a corporate income tax rate of 25%. In accordance with the income tax rate reconciliation and disaggregation requirements of ASU 2023-09, the Company evaluates income taxes paid by jurisdiction rather than solely by domicile.

Pursuant to the Company's transfer pricing arrangements, DBV incurred and paid U.S. income taxes representing 100% of total income taxes paid for fiscal year ended December 31, 2025 and December 31, 2024. Accordingly, the United States is presented as a separate significant jurisdiction. Income taxes paid in other foreign jurisdictions are aggregated within the "Foreign" category, with Australia comprising the remaining foreign taxes paid.

		December 31,			
		2025		**2024**	
Income (loss) from continuing operations before income tax expense (Benefit)					
France		**(147,065)**		**(113,898)**	
US		**569**		**34**	
Australia		**40**		**—**	
	Total	**(146,456)**		**(113,863)**	
Current tax expense (benefit)					
France		—		—	
US		443		55	
Australia		49		—	
	Total Current tax expense (benefit)	*491*		*55*	
	Total deferred tax expense (benefit)	**—**		**—**	
	Total income tax expense (benefit)	**491**		**55**	
Pre-Tax Income (Loss) :		(146,456)		(113,863)	
French Federal statutory income tax rate / Expense (Benefit)		(36,614)	25.0%	(28,466)	25%
Domestic federal reconciling items					
	Valuation Allowance	41,524	(27.5)%	28,303	(24.86)%
	Issuance costs	**(4,738)**	2.4%		—%
	Other	(20)	—%	209	(0.2)%
Foreign Tax effects					
	USA	300	(0.2)%	9	—%
	Australia	47	—%	—	—%
Effective Tax Expense (Benefit) :		**491**	**(0.3)%**	**55**	**—%**

Deferred Tax Assets

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	December 31,	
	2025	**2024**
Deferred tax assets:		
Net operating loss carryforwards	364,172	316,489
Share-based compensation	1,124	7,344
Others	550	1,316
Total deferred tax assets	**365,846**	**325,150**
Less: Valuation allowance	(365,846)	(325,150)
Net deferred tax assets	—	—

Note 16 Commitments

In connection with the launch of our clinical trials we have entered into service agreements with several CROs. As of December 31, 2025, expenses associated with the ongoing trials amounted globally to $32.7 million, and we had non-cancellable contractual obligations with CROs amounting to 89.8 million.

The Company has entered into multi-year supply and manufacturing agreements that include minimum purchase obligations over defined periods. Under applicable accounting guidance, take-or-pay commitments are generally considered firm purchase commitments but remain off-balance sheet unless they create an unavoidable or unconditional payment obligation, or become loss contract.

With Sanofi

On August 29, 2025, the Company entered into the Supply Agreement with SANOFI under which SANOFI will manufacture and supply the Viaskin® Peanut API exclusively for DBV Technologies S.A. during the agreement term. Under such, the Company has agreed to certain minimum purchase levels and service fees over the initial 4-year-term.

As of December 31, 2025, total payments made during the period under the Supply Agreement were approximately $8.6 million, which were recorded as R&D expenses. The Company will expense manufacturing and supply costs as incurred.

With Fareva

On March 17, 2026, DBV Technologies S.A. entered into the MS Agreement with FLV, under which FLV will manufacture and supply PSM, exclusively for DBV Technologies S.A. during the agreement term. The term is effective for a period of eight (8) years and can be renewed for a period of two (2) years .

As of December 31, 2025, total payments made during the year under the MS Agreement are approximately $1.4 million, which were recorded as detailed in **Note 1 Nature of the business and principles and accounting methods, Significant contracts**.

The following table presents our material expenses commitments for future periods:

	2026	**2027**	**2028**	**Thereafter**	**Total**
			(Amounts in million)		
Purchase obligations - Obligations Under the Terms of CRO Agreements	26.6	22.0	22.1	19.1	89.8
Purchase obligations - Obligations Under the Terms of CMO Agreements	17.4	15.6	15.7	—	48.7
Total	**44.0**	**37.6**	**37.8**	**19.1**	**138.5**

Letter of Credit and Collateral

A Certificate of Deposit, for an initial amount of $0.3 million was signed in order to guarantee an American Express credit cards program in the United States.

Note 17 Relationships with Related Parties

The compensation amounts for 2025 presented below, which were awarded to the Directors and Officers of the Company totaled $14.4 million. The recipients of this compensation are “related parties”.

	December 31,	
	2025	**2024**
Short-term benefits	7,297	5,836
Post-employment benefits	36	34
Termination benefits	—	—
Share-based payments	7,070	2,642
Total	**14,403**	**8,512**

The methods for the valuation of the benefit related to share-based payments are presented in Note 11 Share-Based Payments.

Amounts payable to related parties as of December 31, 2025 and 2024 are as follows:

	December 31,	
	2025	**2024**
Compensation	2,990	1,532
Pension obligations	97	103
Total	**3,087**	**1,635**

No significant related-party transactions were identified during the financial years ended December 31, 2025 and 2024. Recent events relating to related parties are presented in ***Item 7. Governance.***

The information presented for 2025 includes employer social security contributions due in respect of these rewards.

The parent company, DBV Technologies S.A., entered into a cash-pooling agreement with its subsidiaries (DBV Technologies Inc., DBV Technologies Australia Pty Ltd and DBV Pharma SAS), the balance of which amounts to the following as at year-end:

	December 31,	
	2025	**2024**
Loans & Advances	1,800	2,112
Total	**1,800**	**2,112**

Note 18 Loss Per Share

The basic loss per share is calculated by dividing the net loss attributable to the shareholders of the Company by the weighted average number of ordinary shares outstanding during the course of the fiscal year. As the Company was in a loss position for the years ended December 31, 2025 and 2024, the diluted loss per share is equal to basic loss per share because the effects of potentially dilutive shares were anti-dilutive given the Company's net loss.

The computations for basic and diluted loss per share were as follows (in thousands of U.S. Dollars except share and per share data):

	December 31,	
	2025	**2024**
Net loss	(146,947)	(113,918)
Weighted average number of ordinary shares	139,574,259	96,995,379
Net loss per share attributable to ordinary shareholders, basic and diluted ($/share)	**(1.05)**	**(1.17)**

The following is a summary of the ordinary share equivalents which were excluded from the calculation of diluted net loss per share for the periods indicated in number of potential shares. This summary also gives an overview of all exercisable instruments generated by the company either through Financing or incentive programs for employees as described in Note 12.

	December 31,			
	2025		**2024**	
	Warrants	*Shares **	*Warrants*	*Shares **
Non-employee warrants	**107,008**	**107,008**	**244,693**	**244,693**
Employee warrants				**—**
Stock-options	**14,104,578**	**14,104,578**	**10,452,903**	**10,452,903**
Restricted stock units	**3,608,347**	**3,608,347**	**2,813,366**	**2,813,366**
Prefunded warrants	**137,991,871**	**202,972,492**	**22,266,331**	**22,266,331**
PFW 2022	13,116,331	13,116,331	22,266,331	22,266,331
BSA from ABSA (March 20205 PIPE Financing)	15,635,172	27,361,551		
PFW1 from PFW-BS-PFW (March 20205 PIPE Financing)	38,234,712	38,234,712		
BS from PFW-BS-PFW (March 20205 PIPE Financing)	35,348,260	61,859,455		
PFW2 (March 20205 PIPE Financing)	35,657,396	62,400,443		
Total Shares		**220,792,425**		**35,777,293**

** The equivalent in shares*

Note 19 Reportable Segment Disclosure

Viaskin Peanut Segment	December 31,	
	2025	2024
Clinical studies	45,893	41,748
BLA & Regulatory	10,624	7,871
Medical Affairs & Other Medical	10,096	7,316
Research & Innovation	1,957	2,011
Manufacturing & Supply and Quality	48,112	30,396
Sales & Marketing	3,222	2,660
General & Administrative	32,788	28,738
Total expenses	**152,692**	**120,740**

The Company operates and is managed as one operating segment driving expenses for the development of Viaskin Peanut. The Company's R&D organization is primarily responsible for the development and registration efforts of Viaskin Peanut. The Company is also supported by corporate staff functions.
The Company's Chief Executive Officer as the chief operating decision maker ("CODM") manages and allocates resources to the operations of the total company by assessing the overall level of resources available and how to best allocate them to support the Company's long-term company-wide strategic goals. In making this decision, the CODM uses consolidated financial information for the purposes of evaluating performance, allocating resources, setting incentive compensation targets and planning and forecasting for future periods.

The CODM's analysis includes a comparison to budgeted results. Segment assets provided to the CODM are consistent with those reported on the Consolidated Statement of Financial Position with particular emphasis on the Company's available liquidity including cash, cash equivalents.

Note 20 Events after the Close of the Fiscal Year

March 2025 PIPE Financing - January 16, 2026
The Company has received, the supplemental gross proceeds of $94 million (€81 million) resulting in the Full Exercise of the ABSA Warrants and BS Warrants Issued on its March 2025 Financing.

Manufacturing Supply Agreement - PSM "Peanut Source Material " Fareva La Vallée - March 17, 2026

The Company entered into a the MS Agreement with FLV, under which FLV will manufacture and supply the PSM exclusively for DBV Technologies S.A. during the agreement term. The term is effective for a period of eight (8) years and can be renewed for a period of two (2) years.