

**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, 2022

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

State or other jurisdiction of

incorporation or organization

177-181 avenue Pierre Brossollette

Montrouge 92120 France

(Address of principal executive offices)

Not applicable  
(I.R.S. Employer  
Identification No.)

Registrator'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 Depository Shares, each representing one-half of one ordinary share, 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 Depository 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  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 in 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 Depository Share, or ADS, of the registrant's ADSs on The Nasdaq Global Select Market on June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter) was \$ 324.02 million.

As of December 31, 2022, the registrant had 94,137,145 ordinary shares, nominal value €0.10 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement, or Proxy Statement, for its 2023 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, 2022, 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," "continues" 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:

- the impact of the COVID-19 pandemic, including the emergence of new variant strains of COVID-19, and its effects on our operations, research and development, clinical trials and ability to obtain financing and potential disruption in the operations and business of third-party manufacturers, contract research organizations, or CROs, other service providers and collaborators with whom we conduct business;
- 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, or the FDA;
- the timing and anticipated results of interactions with regulatory agencies;
- the 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;

---

[Table of Contents](#)

- our 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 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 limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations.
- COVID-19 may materially and adversely affect our business and our financial results.
- 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 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.

---

[Table of Contents](#)

- 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, which 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 outside of food allergies, 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, 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 Global Select Market, or 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.

TABLE OF CONTENTS

|  |     |
|--|-----|
| <a href="#">Special Note Regarding Forward Looking Statements</a>  | i   |
| <a href="#">Risk Factor Summary</a>  | iii |
| PART I   |     |
| <a href="#">Item 1. Business</a>   | 1   |
| <a href="#">Item 1A. Risk Factors</a>  | 39  |
| <a href="#">Item 1B. Unresolved Staff Comments</a>   | 92  |
| <a href="#">Item 2. Properties</a>   | 93  |
| <a href="#">Item 3. Legal Proceedings</a>  | 93  |
| <a href="#">Item 4. Mine Safety Disclosures</a>  | 94  |
| PART II  |     |
| <a href="#">Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a> | 94  |
| <a href="#">Item 6. (Reserved)</a>   | 95  |
| <a href="#">Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>                        | 95  |
| <a href="#">Item 7A. Quantitative and Qualitative Disclosures About Market Risk</a>  | 110 |
| <a href="#">Item 8. Financial Statements and Supplementary Data</a>  | 110 |
| <a href="#">Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>                         | 110 |
| <a href="#">Item 9A. Controls and Procedures</a>   | 110 |
| <a href="#">Item 9B. Other Information</a>   | 111 |
| <a href="#">Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</a>   | 111 |
| PART III   |     |
| <a href="#">Item 10. Directors, Executive Officers and Corporate Governance</a>  | 111 |
| <a href="#">Item 11. Executive Compensation</a>  | 111 |
| <a href="#">Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>              | 111 |
| <a href="#">Item 13. Certain Relationships and Related Transactions, and Director Independence</a>                                   | 112 |
| <a href="#">Item 14. Principal Accounting Fees and Services</a>  | 112 |
| PART IV  |     |
| <a href="#">Item 15. Exhibits and Financial Statement Schedules</a>  | 112 |
| <a href="#">Signatures</a>   | 116 |

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™", "EPIT™" 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 clinical-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'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.

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

We have earlier-stage food allergy programs including Viaskin Milk, which is in Phase 2 of clinical development for Cow's Milk Allergy and Eosinophilic Esophagitis, or EoE.

**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 for toddlers and children with peanut allergy.**
- **Seek regulatory approval for Viaskin Peanut 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.**

**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, peanut allergy 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

---

**Table of Contents**

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 therefore 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, strict 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 3 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 recent survey conducted across eight European countries reported high rates of frustration, stress and isolation 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 epicutaneous immunotherapy, or EPIT, oral immunotherapy, or OIT, (both with and without adjunctive therapies), and sublingual immunotherapy, or 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 initiate 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 4–17 years. 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.

There remains an unmet need for additional therapies for patients with 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. For example, in the case of respiratory allergies, symptomatic and maintenance allergy treatments, such as antihistamines, bronchodilators and corticosteroids, are available and all among the most widely used treatments in the world.

**Our Viaskin Technology Platform**

Over the last decade, 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 dermal patch containing a small (micrograms) dose of food protein. This technology platform, which we call Viaskin, is an innovative approach to potentially treating 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 Langerhans cells, as well as dermal dendritic cells, thus limiting exposure to the bloodstream. In experimental models, EPIT induced a population of regulatory T cells, or Tregs, with specific properties that resulted in suppression of allergic

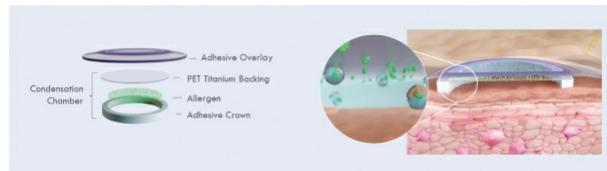
---

[Table of Contents](#)

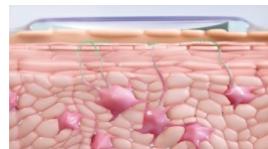
symptoms and protection against further sensitizations. EPIT-induced epigenetic modifications favored a Treg- mediated immune response and a downregulated Th2 response and may play a role in the sustainability of effect. Based on our trials and research, we believe that EPIT has the potential to provide all of 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, which are 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 condensation chamber formed between the skin and the center of the patch creates hyperhydration of the skin and an accumulation of water.
- The accumulation of water solubilizes the allergen. Due to this condensation chamber, the epidermis becomes more permeable allowing passage of the allergen into the epidermis.



Once in the epidermis, the allergen is captured by a population of highly specialized cells: Langerhans cells. These cells can take the protein at the surface of the skin, process it and present its epitopes to the lymphocytes in the lymph nodes.



### 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   | Trial                               | Phase 2 | Phase 3 |
|--|-------------------------------------|---------|---------|
|  | PEPITES: Ages 4-11 years            |         | ●       |
|  | PEOPLE: Ages 4-11 years             |         | ●       |
|  | REALISE: Ages 4-11 years            |         | ●       |
| Viaskin Peanut (DBV712) - Peanut Allergy   | VITESSE: Ages 4-7 years             | ●       | ○       |
|  | Safety study: Ages 4-7 years        |         | ○       |
|  | EPITOFIE: Ages 1-3 years            |         | ●       |
|  | EPOPEX: Ages 1-3 years              |         | ●       |
| Viaskin Milk (DBV135) - Cow's Milk Allergy   | MILES: Ages 2-17 years              | ●       |         |
| Viaskin Milk (DBV135) - Eosinophilic Esophagitis   | SMILEE: Ages 4-17 years             | ●       |         |
| Non-IgE Mediated Cow's Milk Allergy Diagnostic Test (DBV1605) with Nestle Health Science | ARITITUDE: Ages 6 months to 5 years | ○       |         |

● Complete ○ Ongoing ○ Planned

#### Viaskin Peanut for children ages 4-11

Our lead product candidate, Viaskin Peanut, has completed a global Phase 3 development program for the treatment of peanut allergic patients four to 11 years of age. The program comprised 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 two additional years, while patients who received placebo during PEPITES were treated with Viaskin Peanut 250 µg for three years.

The results from PEPITES and REALISE formed the basis for our 2019 regulatory submission in the United States, a Biologics License Application, or 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, or MAA, for the use of Viaskin Peanut in peanut- allergic patients four to 11 years of age.

#### United States Regulatory History

Viaskin Peanut has 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.

---

## Table of Contents

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 October 2019, we announced the FDA's acceptance for review of our BLA for Viaskin Peanut, with a target action date, provided by the FDA, of August 5, 2020.

In February 2020, the FDA announced an Allergenic Products Advisory Committee meeting to be held on May 15, 2020 to discuss the BLA for Viaskin Peanut. On March 16, 2020, we announced that the FDA had informed us that during its ongoing review of our BLA for Viaskin Peanut, it had identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the Advisory Committee meeting to discuss the BLA originally scheduled on May 15, 2020 was cancelled.

In August 2020, we received a Complete Response Letter, or CRL, in which the FDA indicated it could not approve the Viaskin Peanut BLA in its current form. The FDA identified concerns regarding the impact of patch- site adhesion on efficacy and indicated the need for patch modifications, and subsequently a new human factor study. The FDA also indicated that supplementary clinical data would need to be generated to support the modified patch. In addition, the FDA requested additional Chemistry, Manufacturing and Controls, or CMC, data. The FDA did not raise any safety concerns related to Viaskin Peanut.

In January 2021, we received written responses from the FDA to questions provided in the Type A meeting request we submitted in October 2020 following the CRL. The FDA agreed with our position that a modified Viaskin Peanut patch should not be considered as a new product entity provided the occlusion chamber of the current Viaskin Peanut patch and the peanut protein dose of 250 µg (approximately 1/1,000 of one peanut) remains unchanged and performs in the same way it has performed previously. In order to confirm the consistency of efficacy data between the existing and a modified patch, FDA requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. We named that assessment EQUAL, which stands for Equivalence in Uptake of Allergen. The FDA also recommended conducting a 6-month, well-controlled safety and adhesion trial to assess a modified Viaskin Peanut patch in the intended patient population. We later named this clinical trial STAMP, which stands for Safety, Tolerability, and Adhesion of Modified Patches.

Based on the January 2021 FDA feedback, we defined three parallel workstreams:

1. Identify a modified Viaskin patch (which we call mVP).
2. Generate the 6-month safety and adhesion clinical data FDA requested via STAMP, which we expected to be the longest component of the mVP clinical plan. We prioritized the STAMP protocol submission so we could begin the clinical trial as soon as possible.
3. Demonstrate the equivalence in allergen uptake between the current and modified patches in the intended patient population via EQUAL. The complexity of EQUAL hinged on the lack of established clinical and regulatory criteria to characterize allergen uptake via an epicutaneous patch. To support those exchanges, we outlined our proposed approach to demonstrate allergen uptake equivalence between the two patches, and allotted time to generate informative data through two additional Phase 1 clinical trials in healthy adult volunteers:
  - a. PREQUAL, a Phase 1 trial with adult healthy volunteers to optimize the allergen sample collection methodologies and validate the assays we intend to use in EQUAL. The data collection phase of the trial is complete, and the data analysis phase is ongoing.
  - b. 'EQUAL in adults,' a second Phase 1 trial with adult healthy volunteers to compare the allergen uptake of cVP and mVP.

In March 2021, we commenced CHAMP (Comparison of adHesion Among Modified Patches), a Phase 1 trial in healthy adult volunteers to evaluate the adhesion of five modified Viaskin Peanut patches. We completed

---

## Table of Contents

CHAMP in the second quarter of 2021. All modified Viaskin Peanut patches demonstrated better adhesion performance as compared to the then-current Viaskin Peanut patch, and based on the results of CHAMP, we then selected two modified patches that performed best out of the five modified patches studied for further development. We then selected the circular patch for further development, which is approximately 50% larger in size relative to the current patch and circular in shape.

In May 2021, we submitted our proposed STAMP protocol to the FDA, and on October 14, 2021, we received an Advice/Information Request letter from the FDA. In this letter, the FDA requested a stepwise approach to the modified Viaskin patch development program and provided partial feedback on the STAMP protocol. Specifically, the FDA requested that we conduct allergen uptake comparison trials (i.e., 'PREQUAL in Adults,' PREQUAL), and submit the allergen uptake comparison data for FDA review and feedback prior to starting the STAMP study. The FDA's explanation was that the results from the allergen uptake trials might affect the design of the STAMP study.

After careful review of the FDA's information requests, in December 2021, we decided not to pursue the sequential approach to the development plans for Viaskin Peanut as requested by the FDA in the October 2021 feedback. We estimated that the FDA's newly proposed sequential approach would require at least five rounds of exchanges that necessitate FDA alignment prior to initiating STAMP, the 6-month safety and adhesion study. As such, in December 2021, we announced our plan to initiate a pivotal Phase 3 placebo-controlled efficacy trial for a modified Viaskin Peanut patch (mVP) in children in the intended patient population. We consider this approach the most straightforward to potentially demonstrate effectiveness, safety, and improved *in vivo* adhesion of the modified Viaskin Peanut system. The FDA confirmed our change in strategy was agreeable via oral and written exchanges. In 2022, we announced the new Phase 3 pivotal study of the modified Viaskin Peanut (mVP) patch would be in younger (4-7 years old) and more sensitive children with peanut allergy.

### *European Union Regulatory History*

In November 2020, we announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut, submitted under the name "Abylgis®," had been validated by the European Medicines Agency, or EMA. The validation of the MAA confirmed that the submission was sufficiently complete to begin the formal review process for Viaskin Peanut to treat peanut allergies in children ages four to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, on whether to grant a marketing authorization. On March 11, 2021, we announced that we had received the EMA's Day 120 questions, which were consistent with both our expectations and pre-filing conversations with the EMA. We did not receive questions about the impact of adhesion on efficacy.

On August 2, 2021, we announced we had received from the EMA the Day 180 list of outstanding issues, which is an established part of the prescribed EMA review process. It is a letter that is meant to include any remaining questions or objections at that stage in the process. The EMA indicated many of their objections and major objections from the Day 120 list of questions had been answered. One major objection remained at Day 180. The Major Objection questioned 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 "Abylgis," and formally notified the EMA of our decision. The initial filing was supported by data from a single, placebo-controlled Phase 3 pivotal trial known as PEPITES (V712-301). The decision to withdraw was based on the view of CHMP that the data available to date from a single pivotal clinical trial were not sufficient to preclude a Major Objection at Day 180 in the review cycle. We believe data from a second Viaskin Peanut pivotal clinical trial will support a more robust path for licensure of Viaskin Peanut in the EU. We intend to resubmit the MAA when that data set is available.

**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 2 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 double-blind, placebo-controlled food challenge, or 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 eliciting dose, or ED. The median baseline reactive dose in PEPITES was 100 mg at baseline.

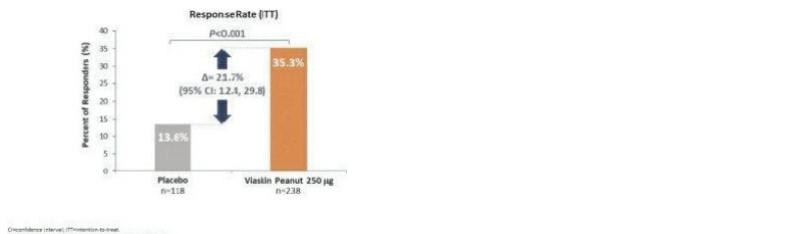


\*Medical history evaluated as currently off treatment at baseline. PEPITES patients, active/peanut 250 µg: 238 (67%); placebo: 118 (33%). Allergic rhinitis: dermatitis: 81.2% (239/298); asthma: 43.5% (131/298); male: 61.2% (148/238); female: 38.8% (90/238).   
 †PEPITES Difl et al. J Allergy Clin Immunol 2018; 141: 101-108.e1-108.e12.

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, 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 of peanut protein, or CRD, 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. Detailed results were published in The Journal of the American Medical Association in February 2019.



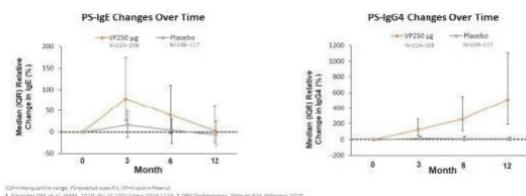
Correspondence interval: ITT intention-to-treat.  
S. Fischer DM, et al. JAMA 2018; doi:10.1001/jama.2018.1115.

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 and 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.

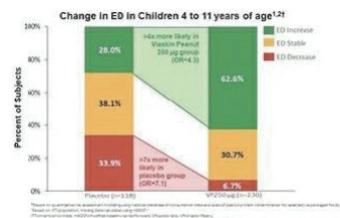


Exploratory analyses showed that changes in peanut-specific biomarkers, including immunoglobulin E, IgG4, and immunoglobulin G4, support the immunomodulatory effect with Viaskin Peanut. The median observed increase from baseline in peanut-specific IgE was greater in the Viaskin Peanut group vs placebo group, respectively, at month 3 (70.1 kilounits of antibody per liter, or kU/L vs. 9.8 kU/L) and month 6 (27.4 kU/L vs. 1.32 kU/L). However, at month 12, peanut-specific IgE levels were observed to return to near baseline in both groups (1.1 kU/L vs. -1.1 kU/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



In a post-hoc analysis, the majority of patients 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 patients 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, or 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%.



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 patients completing the trial. There was a low discontinuation rate due to treatment-emergent adverse events, or 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

[Table of Contents](#)

patients (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 patients continued on Viaskin Peanut in the trial.

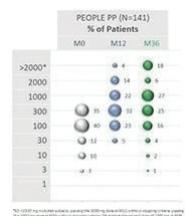
Following the completion of PEPITES, all patients were eligible to enroll in PEOPLE ( *Open-Label Follow-Up Study of the PEPITES Study to Evaluate the Long-term Efficacy and Safety of Viaskin Peanut*), a long-term, open-label extension trial of Peanut 250 µg in children. In the PEOPLE trial, patients who were randomized and received active treatment during PEPITES received Viaskin Peanut 250 µg for two additional years, while patients who previously received placebo during PEPITES will be 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%) patients who completed PEPITES enrolling in this follow-up trial.

**PEOPLE (PEPITES Open Label Extension Study)**

In January 2020, we announced positive topline results of the three-year, open-label extension of our Phase 3 PEPITES trial, or PEOPLE trial, 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 eliciting dose, or ED, which may decrease the chance of reacting to an accidental peanut exposure.

The PEOPLE trial, which completed in October 2022, is an open-label extension 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. 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 patients completed all treatment according to the clinical trial protocol without major deviations. Efficacy data were analyzed from these 141 patients (per-protocol). The last patient last visit of the PEOPLE trial occurred on October 12, 2022.

Topline results from 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 patients 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 patients completed the food challenge without meeting stopping criteria at 36 months (cumulative dose of 5,444 mg). At Month 36, the mean cumulative reactive dose (CRD) was 1,768.8 mg (median 944 mg) compared to 223.8 mg (median 144 mg) at baseline.



The safety profile of Viaskin Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. 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 patient experienced one case of mild anaphylaxis that was

---

**Table of Contents**

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  $\geq 1,000$  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  $\geq 1,000$  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  $\mu$ g in routine clinical practice. REALISE is a multicenter, randomized 3:1, double-blind, placebo-controlled Phase 3 trial, in which pediatric peanut allergic patients were treated with Viaskin Peanut 250  $\mu$ g or placebo for six months. 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. Patients 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 is safety as measured by adverse events, treatment-emergent adverse events and serious adverse events after six months of blinded treatment. Secondary endpoints included evolution of peanut-specific serological markers over time, including IgE, IgG and skin prick test wheel. Exploratory criteria also included scores from patients' Food Allergy Quality of Life Questionnaire, or FAQLQ, and the Food Allergy Independent Measure, FAIM.

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

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

**Results of REALISE Trial**

Results from the 6-month blinded portion of this trial were comparable with outcomes from previous trials of Viaskin Peanut 250  $\mu$ g. 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 patients in the placebo arm (2.0%). One case in one patient in the active arm was qualified by the investigator as moderate anaphylaxis probably related to treatment. The patient 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 patient 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 American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting.

**Viaskin Peanut for Children ages 1-3**

We are also developing Viaskin Peanut for the treatment of peanut allergy in toddlers one to three years of age. In August 2017, we initiated Part A of the EPITOPE (EPIT in Toddlers with Peanut Allergy) trial of Viaskin

[Table of Contents](#)

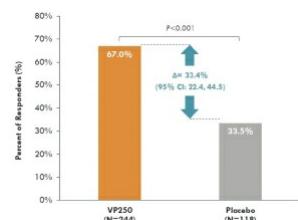
Peanut. EPITOPE is a two-part, pivotal Phase 3 clinical trial assessing the safety and efficacy of Viaskin Peanut 250 µg for the treatment of peanut-allergic toddlers one to three years of age.

In September 2018, we announced that the independent data safety and monitoring board, or DSMB, completed its review of Part A of EPITOPE and recommended that the dose of Viaskin Peanut 250 µg be evaluated in Part B. On October 26, 2018, we announced that the first patient was enrolled in Part B of EPITOPE.

On June 26, 2020, we announced that in Part A, patients in both treatment arms showed consistent treatment effect after 12 months of therapy, as assessed by a double-blind placebo-controlled food challenge and biomarker results. Part A subjects were not included in Part B and the efficacy analyses from Part A were not statistically powered to demonstrate superiority of either dose versus placebo. These results validate the ongoing investigation of the 250 µg dose in this age group, which is the dose being studied in Part B of the study. Enrollment of Part B of EPITOPE was complete in first quarter of 2021.

In June 2022, we announced positive topline results from Part B of 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 (DBPFC) 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  $\leq$  10 mg who reached an ED  $\geq$  300 mg of peanut protein at month 12, or a subject with a baseline ED  $>$  10 mg who reached an ED  $\geq$  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%).



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 3 subjects (2.5%) in the placebo arm experienced a serious adverse event (SAE). Only 1 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.

---

**Table of Contents**

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, 3 resolved with a single dose of epinephrine and 1 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.

We plan to present full EPITOPE trial results at future medical congresses as well as submit them for publication in a peer-reviewed journal. In addition, we intend to further analyze the data from EPITOPE and explore regulatory pathways for Viaskin Peanut in children ages 1 to 3 years, given the high unmet need and absence of approved treatments for this vulnerable population.

We initiated the EPOPEX trial, which is an ongoing open-label extension study evaluating the long-term clinical benefit and safety of Viaskin Peanut 250 mg in subjects who have completed the Phase III EPITOPE trial.

**Viaskin Peanut for Children ages 4-7**

We will evaluate the modified Viaskin Peanut patch in children ages 4-7 years with peanut allergy in two Phase III clinical trials with the intent for the trials to support a future BLA submission.

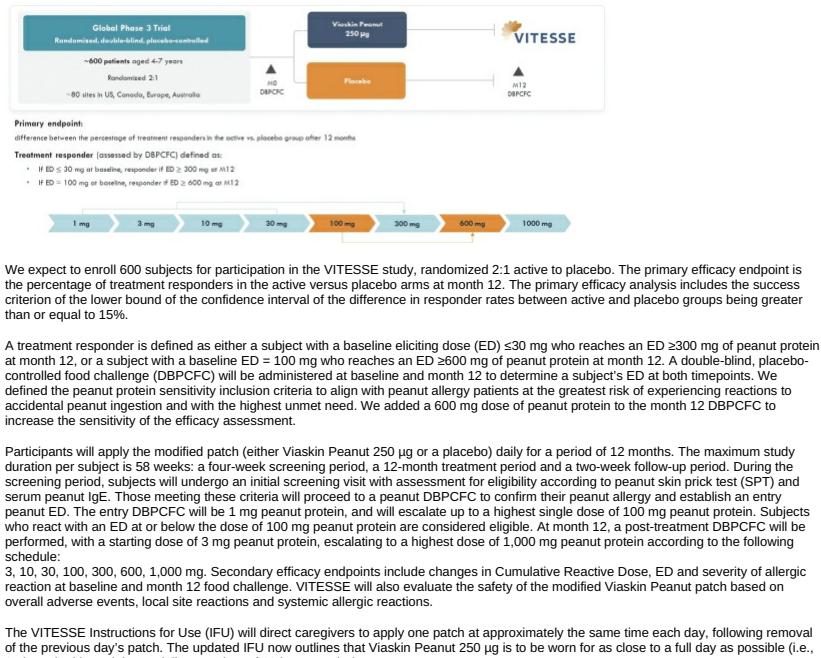
**VITESSE (Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy)**

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)/Ethics Committee (EC) approval.

On September 21, 2022, we announced we had received feedback from the FDA in the form of a partial clinical hold on VITESSE. In the partial clinical hold letter, the FDA specified changes to elements of the VITESSE protocol, acknowledging the intent for the trial to support a future BLA submission. In the following months, we engaged with the FDA to address the feedback provided in the partial clinical hold letter and to finalize the VITESSE protocol. In addition, we continued internal preparations for VITESSE and conducted certain site assessment and start-up activities for prompt study launch once the partial clinical hold was lifted.

On December 23, 2022, we announced the FDA lifted the partial clinical hold and confirmed we satisfactorily addressed all clinical hold issues. The FDA stated that VITESSE may proceed with the revised trial protocol.

Table of Contents



---

## Table of Contents

We expect to initiate patient screening in Q1 2023 with the last patient screened in 1H 2024 and topline results are anticipated in 1H 2025.

### *Safety Study in children ages 4-7 years with peanut allergy*

We plan to initiate a separate safety study in approximately 275 additional subjects, randomized 3:1 active versus placebo. The additional safety data generated by this six-month study will supplement the safety data generated by the VITESSE trial, resulting in a safety database comprised of approximately 600 children ages 4 to 7 years treated with Viaskin Peanut. The protocol design of the safety study will be submitted to the FDA and is expected to be similar to the REALISE (REAL Life Use and Safety of EPIT) safety study that we previously conducted with Viaskin Peanut in children ages 4 to 11 years.

### **Viaskin Milk**

Our second product candidate, Viaskin Milk, is in development for the treatment of cow's milk protein allergy, (IgE-mediated) or CMPA, 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 patients with Immunoglobulin E, or IgE, mediated CMPA, which we refer to as the Milk Efficacy and Safety, or MILES, trial. The MILES (Milk Efficacy and Safety) clinical trial was designed to determine a safe and effective dose in two age groups: children ages two 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, or 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 EoE and as a booster vaccination against *Bordetella pertussis*, or whooping cough, in healthy adults. Our other earlier stage research programs have included vaccination for respiratory syncytial virus, as well as potential treatments for Crohn's disease, celiac disease and type 1 diabetes.

### **Diagnostic Tool Development**

In an effort to continue diversifying our product candidate pipeline, we are also exploring the use of our technology platform in the development of diagnostic tools for food allergies. In May 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAGIC, a ready-to-use and standardized atopy patch test tool for the diagnosis of CMPA (non-mediated IgE) in infants and children under 2 years old. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAGIC up through a pivotal Phase 3 clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAGIC globally. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016. We are currently conducting a Phase 2 clinical trial of MAGIC.

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 are continuing to explore other cellular mechanisms modulated by EPIT™, such as biomarkers, in collaboration with Mount Sinai Hospital in the United States and Commissariat à l'Energie Atomique et aux Energies Alternatives, or CEA, in France. We believe that with improved knowledge about the evolution of immunological biomarkers and epigenetic modulation, we may be able to determine the level of patient response earlier during treatment, ensure follow-up and measure tolerance maintained once treatment is completed. At the 2016 EAACI meeting in Vienna, Austria, we presented initial findings from some of these collaborations, which suggest that proprietary biomarker modeling may be used to help monitor patient responses to Viaskin Peanut. Additional research is being performed to further strengthen the results of these early findings.

**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.

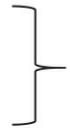
**Viaskin is a Highly Scalable Manufacturing Technology**

We currently rely on a single contract manufacturer to manufacture and supply the active pharmaceutical ingredients ("API") used in our Viaskin product candidates. On February 1, 2018, we entered to a Master API Supply Agreement with Sanofi which sets forth the terms and conditions governing the manufacture and supply of peanut, milk and egg API to be used in our Viaskin product candidates. The agreement expires on a Viaskin product basis five years after the first date of regulatory approval of the applicable Viaskin product candidate and requires us to purchase at least 75% of our required API from Sanofi.

Our manufacturing machine then uses an electrospray technology to deposit the active pharmaceutical ingredient onto the Viaskin patch.



ES GEN3.2 and ES GEN3.3  
From 54 to 72 nozzles  
Used for patches manufacturing for clinical trials.



ES GEN4.0  
288 nozzles  
Used for clinical batches and potential commercial products.

We believe our proprietary Viaskin manufacturing technology creates 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 contract third- party manufacturers to operate it.

We currently rely on a single contract manufacturer, FAREVA Amboise ("FAREVA"), to manufacture and supply clinical and commercial batches of Viaskin Peanut patches. We have entered into a Development Services Agreement, dated August 1, 2015, as amended (the "Development Agreement"), with FAREVA setting forth the terms and conditions whereby DBV selected FAREVA as its contract manufacturing organization to implement the Viaskin production process and to manufacture and supply to DBV batches of finished product for validation and clinical purposes. 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 have agreed with FAREVA to delay implementation of the Commercial Supply Agreement through December 31, 2024, unless we, at our option, decide to reinstate the Commercial Supply Agreement sooner.

#### 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 allergen desensitization methods, have been issued in the major markets, including in particular the United States, Europe, Canada and Australia.

These patents and applications generally fall into four broad categories:

- two patents and patent applications relating to the Viaskin electrostatic patch and its use, half of which expired in 2022;

---

**Table of Contents**

- patents and patent applications which we own relating to our electrospray method of manufacturing the Viaskin electrostatic patch, which may expire as early as 2029;
- patents and patent applications we co-own with AP-HP and the Université Paris Cité (formerly Université de Paris-Descartes, prior to merger and name change) relating to the treatment of peanut, milk, egg, and other allergies using our Viaskin patch technology, which may expire as early as 2028; and
- a variety of other patent applications that we own or co-own relating, for example, to prophylactic uses of the Viaskin patch technology and to treatment of other indications using the Viaskin patch technology.

***U.S. Patent Term Restoration 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 restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration 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 extension.

The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the 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 drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its 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 device 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 if extended. We also have extensive know-how and trade secrets covering part of the Viaskin patch manufacturing method using electrospray technology.

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, or BPCIA. Biosimilarity, which 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 product and the reference product in terms of safety, purity, and potency, which can be shown through analytical studies, animal studies, and a clinical trial or trials. 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 or interchangeable 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

---

[Table of Contents](#)

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.

In the European Union, article 14 (11) of the regulation (EC) No. 726/2004 provides that, without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorized in accordance with the provisions of this regulation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection, in which connection the latter period shall be extended to a maximum of 11 years if, during the first eight years of those ten years, 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.

**Co-Ownership Agreement**

**AP-HP and Université de Paris-Descartes**

In December 2008, we entered into an assignment, development and co-ownership agreement with AP-HP and Université Paris-Descartes, or UPD (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 used in the product. 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 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 license 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 agreement will automatically terminate upon the expiration of the last shared patent. In the event the agreement is terminated, 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 the shared patents would survive termination of the agreement. The longest lived patent rights licensed to us under the agreement are currently expected to expire in 2031, absent patent term extension.

**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 oral, or OIT; sublingual, or SLIT; subcutaneous, or SCIT; or intransal immunotherapy, synthetic or denatured allergens, medicinal herbs, 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 approved by the FDA and the European Commission: Palforzia, a formulation of peanut flour developed by Aimmune Therapeutics, Inc., or Aimmune. Nestlé S.A., with whom we have an existing license and collaboration agreement, acquired Aimmune in October 2020. Aimmune continues to function as a stand-alone business unit that will manage all of Nestlé's global pharmaceutical business.

**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, or FDCA, and the Public Health Service Act, or PHS, 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 Biologics License Application, or 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, or 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, or 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, or 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 non-compliance. Accordingly, we cannot be sure that submission of an IND 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.

---

## Table of Contents

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients 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 and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or serving 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 individuals participating in the clinical trials 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 public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, 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 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 patients 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 for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product 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. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients 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 the clinical trials must be submitted at least annually to the FDA and 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 or if the drug has been associated with unexpected serious harm to 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

---

## Table of Contents

authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. 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 trial completion, trial data 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 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 the biologic 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 may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, 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 are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

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 BLAs within ten months of the filing date for standard review or six months of the filing date for priority review, 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. 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 a recommendation 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 us 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 we may not receive a timely approval, if at all.

---

## Table of Contents

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product 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 all of 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 we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and we 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, or 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

---

[Table of Contents](#)

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. 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.

---

**Table of Contents**

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, 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 Designation***

The Food and Drug Administration Safety and Innovation Act, or 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, or 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, or 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

---

[Table of Contents](#)

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. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

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 System Regulation, or QSR, 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, or 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

---

## Table of Contents

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, our future product candidates may also be 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 European Union are subject to significant regulatory controls. Certain preclinical (also termed "non-clinical") data is required in order to enable clinical trials and later to be used in a dossier for a marketing authorization application. The requisite amount of preclinical data enables the design of a clinical trial, from Phase 1 (first-in-human clinical trials) through to Phases 2 and 3, which are quality, safety and efficacy studies. During all phases of clinical development, national competent authorities of EU Member States and other comparable regulatory authorities require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014, or CTR, which entered into application on January 31, 2022, repealing and replacing the Clinical Trials Directive 2001/20, or CTD. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations governing clinical trials, including the Good Clinical Practice Directive 2005/28. 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, or CTIS. Since January 31, 2023, the use of CTIS has become mandatory for all clinical trial sponsors submitting initial applications for the approval of their clinical trials in the EU. The CTR also

---

## Table of Contents

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 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 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 the concerned 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 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 establishes a general principle according to which information contained in CTIS shall be made publicly accessible unless confidentiality is justified on grounds of necessary to protect personal data, or commercially confidential information, necessary to protect confidential communications between EU Member States in relation to the preparation of an assessment report, or necessary to ensure effective supervision of the conduct of a clinical trial by EU Member States. The confidentiality exception may be overruled if there is an overriding public interest in disclosure. The publication of data and documents in relation to the conduct of a clinical trial will take place in accordance with specific timelines. The timelines are established by the EMA and are determined based on the documents and the categorization of the clinical trial. In addition, sponsors of clinical trials may apply for deferral of publication of certain documents at the time of submission of the initial clinical trial application. The application for deferral of publication should be based on justified grounds and include a reasoned proposed deferral period. Applications for deferral of publication are subject to the approval of concerned EU Member States.

The extent to which on-going clinical trials will be governed by the CTR will depend on the timing at which an application for the authorization of a clinical trial is submitted and the duration of the individual clinical trial. Sponsors can choose to submit a clinical trial application under either the CTD or the CTR until January 31, 2023. For clinical trials in relation to which application for authorization was made on the basis of the CTD before January 31, 2022, the CTD will continue to apply on a transitional basis for three years and, if authorized, those clinical trials will be governed by the CTD until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework.

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, including ATMPs, 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 European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

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

---

[Table of Contents](#)

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU Member States. 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) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto immune 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, or 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 Decentralized Procedures – Human, or 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

---

## Table of Contents

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, or 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.

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 fulfills 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, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which 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

---

## Table of Contents

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, or 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, or PSURs.

All new MAAs must include a risk management plan, or 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.

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, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians 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.

*Combination Products*

In the EU, products that are a combination of a medicinal product and a medical device are regulated as either a medicinal product or a medical device, depending on which component has the primary mode of action.

Medical devices that incorporate a medicinal product as an integral part that has an action ancillary to the action of the medical device are regulated as medical devices in accordance with Regulation (EU) 2017/745 on Medical Devices, or 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 a medical device incorporates a medicinal product as an integral part as a single use drug delivery system, it is regulated as a medicinal product. In this case, the relevant General Safety and Performance Requirements, or GSPRs of the MDR will apply to the safety and performance of the device element.

**Other Regulatory Matters**

*Brexit*

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator. On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement, or Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the Agreement includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the Agreement.

Among the changes that will now occur, Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of the Agreement, the EU and the UK will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use.

Regarding marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. Since January 1, 2021, an applicant for a centralized procedure marketing authorization can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain an MA to market products in the UK. Until December 31, 2023, MHRA may rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization. From January 1, 2024, a new international recognition process, which will have regard to decisions made by the EMA and certain other regulatory, is anticipated to be in place. The MHRA has also established its own decentralized or mutual recognition procedures which enable marketing authorizations approved in EU Member States through decentralized and mutual recognition procedures to be recognised in the United Kingdom or Great Britain. Since Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and

---

## Table of Contents

facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials and marketing authorization is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and 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, we 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.

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. 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. The ACA was expansive health reform legislation designed to expand coverage for the uninsured while at the same time containing overall healthcare costs enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, and other changes. With regard to biopharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program. However, there have been executive, judicial and Congressional challenges to certain aspects of the

---

[Table of Contents](#)

ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction was tasked with recommending to Congress proposals in spending reductions. Because they did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, it triggered the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the Infrastructure Investment and Jobs Act, will stay in effect until 2031, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Additionally, in the United States, there have been several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to Biden’s executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated “maximum fair price” for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand

---

## Table of Contents

and prices for our products, if approved. This could harm our or our collaborators' ability to market any products and generate revenues. Cost containment measures that healthcare payors and providers are instituting and the effect of further healthcare reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses.

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. A 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).

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, or CEPS (failing this, by unilateral decision of the CEPS). A framework agreement has been concluded between LÉEM (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.

---

[Table of Contents](#)

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;
- 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, or 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 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 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 licensure or registration by pharmaceutical sales representatives; state 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 health care 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

---

## Table of Contents

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 European Union's General Data Protection Regulation ((EU) 2016/679), or GDPR, and the United Kingdom's General Data Protection Regulation, or UK GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened.

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 European Union. 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 Euros or 4% of a company's global annual revenue 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.

Following the United Kingdom's withdrawal and the expiration of the transition period, from January 31, 2020, companies doing business in the EU and the UK will be obliged to comply with both the GDPR and the UK GDPR. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision and remains under review by the European Commission during this period. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term.

### **Employees**

As of December 31, 2022, we had 85 full-time employees, including approximately 20 with M.D. or Ph.D. degrees, and 1 part-time employee. Of these employees, 29 employees are engaged in research and development, clinical development and operations, medical affairs, and biostatistics activities and 26 employees are engaged in general and administrative activities. We consider the relationship with our employees to be good. 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 177-181 avenue Pierre Brossolette, 92120 Montrouge, 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, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at [www.sec.gov](http://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 \$96.3 million and \$97.8 million for the years ended December 31, 2022 and 2021 respectively. As of December 31, 2022, we had an accumulated deficit of \$259.6 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, such as conditional advances from OSEO Innovation, or OSEO, 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 European Union. Even if we obtain regulatory approval to market Viaskin Peanut or any other

---

[Table of Contents](#)

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.

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.

Based on our current operations, as well as our plans and assumptions, we expect that our balance of cash and cash equivalents of \$209.2 million as of December 31, 2022 will be sufficient to fund our operations for at least the next 12 months.

We intend to seek 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 due to the COVID-19 pandemic. The COVID-19 pandemic caused extreme volatility and disruptions in the capital and credit 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 are not successful in our financing objectives, we could have to scale back our operations, notably by delaying or reducing the scope of our research and development efforts or obtain financing through arrangements with collaborators or others that may require us to relinquish rights to our product candidates that we might otherwise seek to develop or commercialize independently.

If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations.

***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 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, 2022, our cash and cash equivalents were \$209.2 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 expect our operating losses to continue for the foreseeable future. Based on our current operations, we expect that our current cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months.

We expect that we will need to raise substantial 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 due to the COVID-19 pandemic. The COVID-19 pandemic caused extreme volatility and disruptions in the capital and credit 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.

---

[Table of Contents](#)

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 incurrence 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 May 12, 2022 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 closing price of the Company's shares on the regulated market Euronext Paris during the last trading session, (ii) the volume-weighted average (in the central order book and off-market blocks) of the Company's share price on the Euronext Paris regulated market during the last three trading days, (iii) the average of five consecutive trading days chosen among the last thirty trading sessions, or (iv) the weighted average trading price the day, each of (i) to (iv) 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 such as the COVID-19 pandemic, political crises, geopolitical events, such as the crisis in Ukraine, 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. For example, the COVID-19 pandemic resulted in widespread

unemployment, economic slowdown and extreme volatility in the capital markets. The U.S. Federal Reserve recently 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.

On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the United States and other countries and companies and organizations against officials, individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and responses of countries and political bodies to such sanctions, tensions, and military actions and the potential for more widespread conflict, have resulted in supply chain disruptions, and resulting increases in inflation, financial market volatility and capital markets disruption, potentially increasing in magnitude, and such effects on the global economy and financial markets could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms. In addition, any or all of these effects 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.

***COVID-19 may materially and adversely affect our business and our financial results***

Our business could be materially and adversely affected by the effects of the COVID-19 pandemic in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. The COVID-19 pandemic 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.

As a result of the COVID-19 pandemic, our ability to conduct clinical trials was and may continue to be affected clinical site initiation, patient enrollment and patient visits (including food challenges) in any of our clinical trials may be suspended or delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some patients 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 patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our future clinical trial operations.

The pandemic and related government and private sector responsive actions affected the broader economies and financial markets, triggering an economic downturn, which at points adversely affected, and could again 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 the ongoing spread of COVID-19 could materially affect our business.

It is impossible to predict all effects and the ultimate impact of the COVID-19 pandemic. the full extent of COVID-19's impact on our clinical development and other operations and financial performance depends on continuing developments that are uncertain and unpredictable, including the timing of vaccine rollouts and herd immunity, virus mutations and variants, and any new information that may emerge concerning the 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.

***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 control 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 require, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting. This assessment will include disclosure of any material weaknesses identified by our management in 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;

---

[Table of Contents](#)

- 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 Securities Exchange Act of 1934, or 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 now qualify as a domestic filer. The Exchange Act requires that, as a public company that no longer qualifies as a foreign private issuer, we file annual, quarterly and current reports with respect to our business, financial condition and result of operations. Because we are no longer a foreign private issuer, we will also be required to file proxy statements in connection with any meetings of our shareholders. As a result of being a U.S. public company, 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

---

**Table of Contents**

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 U.S. public company that is subject to these rules and regulations, we may find it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of disclosure of information in filings required of a U.S. public company, particularly as we are no longer a foreign private issuer, our business and financial condition will become 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 Viaskin Milk, and our commercial opportunities may be limited.

We are currently conducting VITESSE, a Phase 3 pivotal study in children aged 4-7 years old with Type V Viaskin Peanut System, of the modified Viaskin Peanut system, which will need to have positive results in order for us to seek regulatory approval before we are permitted to commence its commercialization, if ever. Viaskin Milk will also require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence its commercialization, if ever. Many of 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 is 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 successfully developed or commercialized.

---

[Table of Contents](#)

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 or a waiver from the competent authorities of the EU Member States and/or the EMA. 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 clinical research organizations, or 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 either 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 agency may require development of a Risk Evaluation and Mitigation Strategy (or 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

---

[Table of Contents](#)

our product candidates based on our Viaskin technology platform. Moreover, because our business is almost entirely dependent upon 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:

- a product candidate is ineffective, inferior to existing approved medicines, 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;
- the results may not confirm the positive results of earlier testing or 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 Complete Response Letter, or CRL, in which the FDA indicated it could not approve the Viaskin Peanut BLA in its current form. The FDA identified concerns regarding the impact of systemic adhesion on efficacy and indicated the need for modifications, and a new human factors study. The FDA also indicated that supplementary clinical data would need to be generated to support the modified product, and requested additional Chemistry, Manufacturing and Controls, or 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

---

[Table of Contents](#)

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 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. This consists of giving the offending food protein to patients to assess the sensitivity of their food allergy, and thus evaluate the safety and 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 patients 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 or 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 permission to proceed from the FDA under an investigational new drug, or IND, application, or foreign equivalent approval from regulatory authorities outside the United States;
- obtaining institutional review board, or IRB, approval or positive Ethics Committee opinions as part of the single decision on the authorization of a clinical trial issues 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;

---

[Table of Contents](#)

- determining dosing and clinical design and making related adjustments; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial, and which has been impacted by the COVID-19 pandemic.

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 patients for the sensitivity of their allergies;
- 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 and changes in regulatory requirements, policy and guidelines, including 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 patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients 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 pandemic, 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 in 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, or changes in FDA or other similar foreign regulatory authority policy

---

[Table of Contents](#)

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. 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 pursue that designation for other product candidates as well. If a product is intended for the

---

[Table of Contents](#)

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. 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 which conducts 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.

---

[Table of Contents](#)

***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 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 the 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 Federal Food, Drug, and Cosmetic Act, or 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 for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies, 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;

---

[Table of Contents](#)

- 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;
- the securing of, costs related to, and timing issues associated with, product manufacturing, as well as sales and marketing activities; and
- impacts of the COVID-19 pandemic.

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 patches for our clinical trials or diagnosis patches, and will be necessary 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 as a result of impacts due to the COVID-19 pandemic or other unfavorable global economic conditions, including as a result of the ongoing conflict between Russia and Ukraine. 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 at a minimum a second source of supply for critical raw materials and materials, such as natural protein and polymer film with a titanium coating. 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 active pharmaceutical ingredients, or 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 plans 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

---

[Table of Contents](#)

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 clinic trials may be delayed. Further, we are aware that Sanofi has entered into a clinical collaboration with Regeneron and Aimimmune Therapeutics, to evaluate treatment with Palforzia in combination with Dupilumab in peanut allergic patients, and commenced a Phase 2 clinical trial in October 2018 under this collaboration. This potential competitive dynamic may make Sanofi less inclined to continue or renew their manufacturing arrangement with us on commercially reasonable terms or at all and, notwithstanding contractual protections, Sanofi may be able to utilize knowledge gained through their relationship with us in furtherance of their development of competitive therapies.

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 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 current good manufacturing practices, or 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 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 Quality System Regulation, or 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, such as COVID-19, 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;

---

[Table of Contents](#)

- 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 Biologics Price Competition and Innovation Act, or 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 administered 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. Moreover, the process by which an interchangeable product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products (*i.e.*, drugs) is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing and subject to interpretation.

The European Union provides opportunities for data and market exclusivity related to marketing authorizations. Upon receiving a marketing authorization, 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

---

[Table of Contents](#)

authorities in the European Union 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 marketing authorization application 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 European Union until 10 years have elapsed from the initial marketing authorization of the reference product in the European Union. 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 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. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the European Union, 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.

We also believe that our product candidates in the European Union should benefit from data and market exclusivity. As with the U.S., however, if competitors obtain marketing authorization for their biosimilar products, our products may become subject to competition from these biosimilars, with the attendant competitive pressure and consequences.

***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 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

---

[Table of Contents](#)

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 oral, or OIT, sublingual or SLIT, subcutaneous, or SCIT, or intranasal immunotherapy, or products using synthetic allergens, or denatured allergens, medicinal herbs, 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 anti-IgE monoclonal antibodies treatments 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 with to our products.

There is one treatment for peanut allergy, which has been approved by the FDA and the European Commission: Palforzia, a formulation of peanut flour developed by Aimmune Therapeutics, Inc., or Aimmune. Nestlé S.A., with whom we have an existing license and collaboration agreement, acquired Aimmune in October 2020. Aimmune continues to function as a stand- alone business unit that will manage all of Nestlé's global pharmaceutical business.

***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 drug 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

---

[Table of Contents](#)

that covers our costs, including research, development, manufacture, sales and distribution. Third-party payors are increasingly reducing reimbursements for medical products, drugs and services. 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. 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, including expanded Medicaid eligibility, subsidized insurance premiums, provided incentives for businesses to provide health care benefits, prohibited denials of coverage due to pre-existing conditions, established health insurance exchanges, and provided additional support for medical research. With regard to biopharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA or operations.

Following ACA, both the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, or the ATRA, include, among other things, mandatory reductions in Medicare payments to certain providers. Additionally, in the United States, there have been several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

---

[Table of Contents](#)

Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market any products and generate revenues. Cost containment measures that healthcare payors and providers are instituting and the effect of further healthcare reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses.

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 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. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. 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. Health Technology Assessment, or 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.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. 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. 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; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU Member States. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and

---

[Table of Contents](#)

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, or 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 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 1,000 human patients 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 as 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 the patient, 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 patient 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 the 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.

***The United Kingdom's withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common shares.***

Following the result of a referendum in 2016, the United Kingdom left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the United Kingdom, or the UK, was subject to a transition period until December 31, 2020, or the Transition Period, during which EU rules continued to apply. The UK and the EU have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU's relationship will operate going forwards however there are still many uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

Since a significant proportion of the regulatory framework in the UK which may be applicable to our business and our product candidates is derived from EU Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU, now that UK legislation has the potential to diverge from EU legislation. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates.

into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

***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.
- The federal Health Insurance Portability and Accountability Act of 1996, or 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 the Health Information Technology for Economic and Clinical Health Act, or 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.

---

[Table of Contents](#)

- 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 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 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 licensure or registration of pharmaceutical sales representatives; state 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, such as the national

---

[Table of Contents](#)

competent authorities of EU Member States and Ethics Committees, 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, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). However, the Retained EU Law (Revocation and Reform) Bill published in late 2022 which is intended to remove all EU-derived legislation from the UK statute book by the end of 2023, may result in a divergence of approach between the EU and the UK.

On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the UK.

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 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, such as our exclusive global collaboration with Nestle Health Science, 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;

---

[Table of Contents](#)

- 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.

#### **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 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 provide a basis for 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;

---

**Table of Contents**

- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; 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 ours. 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. 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, 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. 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. 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 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 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.

***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 United States Patent and Trademark Office, or 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 proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. 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, 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 would 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, or the Supreme Court, 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 Supreme Court have issued (or will issue) rules 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, or 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 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 new and untested 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 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 post-grant review. In addition, bills have been introduced that would provide the director of the U.S.P.T.O more authority to set aside PTAB decisions. If these bills are eventually passed by the U.S. Congress, it could impact our ability to enforce/defend patents by allowing third parties more opportunities to challenge them.

***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 and defending 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 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. 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 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 samples, 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, 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.

---

[Table of Contents](#)

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 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 that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant 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 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. 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

---

[Table of Contents](#)

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 patients 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, the regulatory authorities, 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 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.

The complaint, as amended, alleged 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. See the section of this Annual Report titled "Legal Proceedings" for additional information on this matter.

Whether or not the 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.

---

[Table of Contents](#)

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 results of operations.***

As a French technology company, we have benefited from certain tax advantages, including, for example, the French research tax credit (*credit d'impôt recherche*), or 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. During the fiscal year ending December 31, 2022, the Company received the reimbursement of the 2019, 2020 and 2021 fiscal year research tax credit for a total amount of \$26.1 million. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented \$5.7 million and \$7.5 million, as of December 31, 2022 and 2021 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 benefit. 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 incur portions of our expenses, and may in the future derive revenues, in currencies other than the euro, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results

---

[Table of Contents](#)

of operations and cash flows. The ADSs are quoted in U.S. dollars on the Nasdaq Global Select Market and our ordinary shares are trading in euros on Euronext Paris. Our financial statements are prepared in euros. 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.

***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, and consumer protection 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, the California Consumer Privacy Act of 2018, or CCPA, 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 exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020, CPRA, effective January 1, 2023, will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which became

---

[Table of Contents](#)

effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 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, 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. The EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, that the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries, such as the United States, that do not provide an adequate level of personal data protection, and certain 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 the EEA, the UK or other jurisdictions to the United States in a lawful manner, or if the costs for such lawful transfers of personal data are too high, we may face 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 import personal data to the United States could significantly and negatively impact our business operations; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense; or interrupting or adversely impacting our operations.

Our obligations related to data privacy and security 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 upon whom we rely 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.

---

[Table of Contents](#)

If we 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); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data.

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 upon which we rely, 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 upon which we rely. 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 upon which we rely may be vulnerable to a heightened risk of these attacks, including 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 upon which we rely may be subject to a variety of evolving threats, including, but not limited to, social-engineering attacks (including through 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 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 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. Similarly, supply-chain attacks have

---

[Table of Contents](#)

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 or disruption to our information technology systems or the third-party information technology systems that support us and our services. Additionally, the COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations, outside our premises. 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 upon whom we rely. A security incident or other interruption disrupt our ability (and that of third parties upon whom we rely) 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 and remediate vulnerabilities but we may not be able to detect and remediate all vulnerabilities because threats and techniques used to exploit the vulnerability change frequently, 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 to notify relevant stakeholders 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 upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience 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; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant 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 such acquisitions were to become necessary in 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, or 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 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.

***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, 2022, we had 85 full-time employees. Before we can commercialize of 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 price of \$21.64 per share, and the price per ADS has ranged from as low as \$1.08 and as high as \$3.43 during 2022. During this same period, our ordinary share prices have ranged from as low as €2.17 to as high as €5.48. 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, including as a result of the COVID-19 pandemic.

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, 2022, our executive officers, directors, current 5% or greater shareholders and affiliated entities, including entities affiliated with Baker Bros. Advisors LP, entities affiliated with Braidwell, L.P., entities affiliated with VR Adviser, LLC, and entities affiliated with Bpifrance Participations S.A., together beneficially own approximately 52% 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 Global 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 January 14, 2021, we received a notice from Nasdaq indicating that we did not meet Nasdaq's quorum requirement under Listing Rule 5620(c)(i), or the Nasdaq Quorum Requirement, because our bylaws do not require a quorum for shareholders' meetings of at least 33 1/3% of the outstanding shares of our voting ordinary shares. While our ADSs are listed on Nasdaq, our ordinary shares are listed on Euronext Paris. Applicable French laws and regulations prohibit French listed companies from having a quorum requirement for shareholders' meetings that is higher than the minimums set by French law. The minimum quorum requirements under French law are lower than the Nasdaq Quorum Requirement.

In April 2021 following our discussions with Nasdaq, Nasdaq modified the Nasdaq Quorum Requirement, such that Nasdaq will accept a quorum requirement of the home country of a non-U.S. company that is lower than that required by Nasdaq, provided the company fulfill certain requirements. In April 2021, in accordance with the amended Nasdaq Quorum Requirement, we fulfilled such requirements, including filing with the SEC a Current Report on Form 8-K disclosing that we had submitted a letter from our independent French counsel to Nasdaq

stating that the laws of France mandate a lower quorum for shareholders' meetings than that required by the Nasdaq Quorum Requirement, and that we cannot obtain an exemption or waiver from such requirements. We also posted a statement regarding our reliance on the exception from the Nasdaq Quorum Requirement on our website. On April 26, 2021, Nasdaq notified us that we regained compliance with the Nasdaq Quorum Requirement.

Notwithstanding our ability to regain compliance with the Nasdaq Quorum Requirement, 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.

Such a delisting would also likely have a negative effect on the price of our ADSs and would impair your ability to sell or purchase our ADSs when you wish to do so. 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 the market price of the ADSs.***

As of December 31, 2022, 94,137,145 ordinary shares were issued and outstanding. Sales of a substantial number of shares of our ordinary shares or ADSs in the public market, or the perception that these sales might occur, could depress the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our shares are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly.

In June 2022, we completed a \$194 million PIPE financing from the sale of (i) 32,855,669 Ordinary Shares, nominal value €0.10 per share at a price per Ordinary Share of €3.00 (corresponding to \$3.22 on the basis of an exchange rate of \$1.0739 = €1.00 published by the European Central Bank on June 8, 2022), and (ii) pre-funded warrants to purchase an aggregate of 28,276,331 Ordinary Shares (the "Warrant Shares") at a pre-funded price per pre-funded warrant of €2.90 (corresponding to \$3.11), which equals the per share price of the Ordinary Shares less the exercise price of €0.10 per pre-funded warrant. Each pre-funded warrant has an exercise price of €0.10 per Warrant Share. Pursuant to a registration rights agreement (the "Registration Rights Agreement") with the investors, the Company filed a registration statement with the SEC registering the resale of 59,269,629 ordinary shares issued in the PIPE financing, including ordinary shares underlying the pre-funded warrants. The Company also filed a registration statement with the SEC registering the resale of 11,593,170 ordinary shares by Entities affiliated with Baker Bros. Advisors, issued in the PIPE financing, including ordinary shares underlying the pre-funded warrants. As a result, subject to certain beneficial ownership limitations contained in the pre-funded warrants, these shares are freely tradable, without restriction, in the public market. In addition, the exercise of some or all of the pre-funded warrants will increase the number of our outstanding ordinary shares, which may dilute the ownership percentage or voting power of our shareholders.

In addition, we have filed a registration statement with the SEC to register the ordinary shares that may be issued under our equity incentive plans. The ordinary shares subject to outstanding options under our equity incentive plans, ordinary shares reserved for future issuance under our equity incentive plans and ordinary shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our 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 Global Select 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, if 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 participate in this or any other 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 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'Economie*).

In addition, French Decree (Décret) No. 2020-892 of July 22, 2020 as amended by French Decree No. 2020-1729 of December 28, 2020, French Decree No. 2021-1758 of December 22, 2021 and French Decree No. 2022-1622 of December 23, 2022 (i) lowers the scope of application of the foreign investment regime until December 31, 2023 to the crossing of the threshold of 10% of the voting rights of French companies whose shares are admitted to trading on a regulated market and (ii) subjects this new threshold 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 euros (for a

company) or 1 million euros (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 subsidiary, 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 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 Securities Exchange Act of 1934, as amended, or 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 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, or Section 404;
- 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, or 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 may have been a PFIC for the taxable year ending December 31, 2022. 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, 2022 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 U.S. holder (as defined below under "Material Income Tax Considerations—Certain Material U.S. Federal Income Tax Considerations") 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 as a 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, 2021, 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 2. Properties.**

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,470 square meter facility, pursuant to a lease agreement, signed on March 3, 2015, with an effective date of August 1, 2015 and which expires July 31, 2024.

Our primary U.S. office is located in Basking Ridge, New Jersey. On March 28, 2022, we entered into a lease agreement, commencing on April 1, 2022 and effective for 38 months, for an office of 5,799 square feet in Basking Ridge, New Jersey.

The Company leased a commercial facility of 8,919 square feet and an additional 12,629 square feet in the same building in Summit, New Jersey. Both leases were initially intended to support the launch and commercialization of Viaskin Peanut in North America and were co-terminus on July 10, 2028, with extension options of two five-year periods. In light of our global restructuring and the current stage of regulatory interactions regarding Viaskin Peanut, the company entered into a termination agreement for the Summit, New Jersey leases effective on January 31, 2022, in exchange for a one-time lump sum early termination fee.

We also have facilities in North America that were initially intended to support our U.S. subsidiary as well as future commercialization needs. We lease 3,780 square feet of office space in Tower 49, New York, New York. This lease is for a period of 65 months. In light of our global restructuring, the current stage of regulatory interactions regarding Viaskin Peanut, and the ongoing COVID-19 pandemic, we entered into a sublease agreement of this office space in June 2021. The lease and sublease both expire on March 31, 2023.

We consider our facilities to be suitable and adequate for the management and operation of our business. We believe that suitable additional or alternative space will be available to accommodate our future growth.

**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.

*Class Action Complaint Dismissal*

A class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint, as amended, alleged that we and our 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 seek 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.

A hearing was held on July 29, 2021 in the U.S. District Court for the District of New Jersey where the Court entered an order granting our Motion to Dismiss the Second Amended Class Action Complaint without prejudice. As the dismissal was without prejudice, the Plaintiffs repled their case by filing a Third Amended Class Action Complaint on September 30, 2021 in the same Court. We moved to dismiss third amended complaint on December 10, 2021. On July 29, 2022, the Court entered an order granting the Company's Motion to Dismiss the Plaintiff's Third Amended Complaint with prejudice. The Court indicated that the Third Amended Complaint was deficient in a number of ways, failing to allege a violation of the Securities Exchange Act of 1934, and ordered the matter closed. Per court procedural rules, the Plaintiffs had 30 days to appeal the dismissal of the Third Amended Complaint. The Plaintiffs failed to file an appeal of the dismissal of the Third Amended Complaint within the 30-day period and this matter is resolved with finality.

**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 have been 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 February 28, 2023, there were approximately 395 holders of record of our ordinary shares and 2 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.

**Recent Sales of Unregistered Equity Securities**

During the year ended December 31, 2022, we issued the following unregistered securities:

- Pursuant to the authorizations granted by the General Meeting of the Shareholders held on May 12, 2022, the Company offered the opportunity to subscribe for warrants to purchase ordinary shares on May 12, 2022, and on June 9, 2022, the Chief Executive Officer authorized a capital increase for an amount of €3,285,566.90 through the issue of (i) 32,855,669 New Shares with a par value of €0.10 each and (ii) the issuance of 28,276,331 prefunded warrants, with cancellation of shareholders' preferential subscription rights in favor of Braidwell LP, funds advised by Baker Bros. Advisor LP and BpiFrance Participations SA, existing shareholder of the Company and Venrock Healthcare Capital Partners;
- On June 8, 2022, we entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which we agreed to issue and sell to the investors i) 32,855,669 ordinary shares, nominal value €0.10 per share, at a price per ordinary share of €3.00 (corresponding to \$3.22 on the basis of an exchange rate of \$1.0739 = €1.00 published by the European Central Bank on June 8, 2022), and (ii) pre-funded warrants to purchase an aggregate of 28,276,331 ordinary shares (the "Warrant Shares") at a pre-funded price per pre-funded warrant of €2.90 (corresponding to \$3.11), which equals the per share price of the ordinary shares less the exercise price of €0.10 per Pre-Funded Warrant. Each Pre-Funded Warrant has an exercise price of €0.10 per Warrant Share. The Pre-Funded Warrants are exercisable at any time after their original issuance and will expire ten years following their issuance. The exercise price and number of shares of ordinary shares issuable upon exercise of the warrants may be adjusted in certain circumstances, including stock splits, stock

---

**Table of Contents**

dividends, reclassifications and the like. The pre-funded warrants issued in the PIPE provide that the holder of the pre-funded warrants will not have the right to exercise any portion of its pre-funded warrants if such holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of ordinary shares outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"). The holder may increase or decrease the Beneficial Ownership Limitation, provided, however, that the holder may only increase the Beneficial Ownership Limitation by (i) obtaining authorization from the French Ministry of Economy in the event the Beneficial Ownership Limitation is being raised above 9.99%, and (ii) by providing 61 days' notice to the Company, except that in no event will the Beneficial Ownership Limitation exceed 19.99%. The securities issued by us pursuant to the securities purchase agreement and to be issued upon exercise of the warrants were not registered under the Securities Act of 1933, as amended, or the Securities Act, and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. Pursuant to the Registration Rights Agreement, the Company filed a registration statement with the Securities and Exchange Commission registering the resale of 59,269,629 ordinary shares issued in the PIPE financing, including ordinary shares underlying the pre-funded warrants.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act, Regulation S, Regulation D or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

**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 clinical-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'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

---

## Table of Contents

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 nine clinical trials, including four Phase 2 trials and three completed Phase 3 trials. We recently completed a Phase 3 trial of Viaskin Peanut in children ages one to three with peanut allergy and we also have an ongoing Phase 3 trial of Viaskin Peanut in children ages four to seven with peanut allergy.

### Financial Overview

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.

Based on its current operations, plans and assumptions as revised pursuant to 2022 announcements related to EPITOPE Phase 3 study topline results and VITESSE Phase 3 partial clinical hold lift, as well as ATM and PIPE financings, the Company expects that its balance of cash and cash equivalents of \$209.2 million as of December 31, 2022 will be sufficient to fund its operations for at least the next 12 months.

We intend to seek 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 due to the ongoing COVID-19 pandemic and conflict in Ukraine. The ongoing COVID-19 pandemic and conflict in Ukraine have already caused extreme volatility and disruptions in the capital and credit 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 are not successful in our financing objectives, we could have to scale back our operations, notably by delaying or reducing the scope of our research and development efforts or obtain financing through arrangements with collaborators or others that may require us to relinquish rights to our product candidates that we might otherwise seek to develop or commercialize independently.

We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our research, pre-clinical and clinical development of our product candidates, including expanding the scope of our trials for Viaskin Peanut;
- seek regulatory and marketing approvals and pursue commercial activities for Viaskin Peanut, primarily in North America and in the European Union;
- seek regulatory and marketing approvals for our other product candidates that successfully complete clinical trials;
- continue to establish a sales, marketing and distribution infrastructure to commercialize Viaskin Peanut, if approved, and any other products for which we may obtain marketing approval, especially in North America and in the European Union;

- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- initiate and conduct any post-approval clinical trials, if required by the FDA or by the EMA, for our approved products, if any;
- initiate additional pre-clinical, clinical or other studies for our product candidates;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or meet other payments deadlines 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;
- experience any delays or encounter issues with any of the above.

Our financial statements have been prepared on a going concern basis assuming that we will be successful in our financing objectives. As such, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should we not be able to continue as a going concern.

**Impact of COVID-19 on our Business**

The COVID-19 pandemic has adversely affected global economies, financial markets and the overall environment in which we do business. Our ability to conduct clinical trials was and may continue to be affected by any future resurgences of the COVID-19 pandemic. As the full impact of the COVID-19 pandemic on our business continues to develop, we are closely monitoring the global situation. We are unable to predict the full impact that COVID-19 will have on our operations, liquidity and financial results, and, depending on the magnitude and duration of any future resurgences of the COVID-19 pandemic, such impact may be material. Accordingly, current results and financial condition discussed herein may not be indicative of future operating results and trends. For further discussion of the business risks associated with COVID-19, see Item 1A, Risk Factors, within this Form 10-K report.

**Business Trends**

We engage in substantial research and development efforts to develop innovative pharmaceutical product candidates. Research and development expense consists primarily of:

- cost of third-party contractors such as contract research organizations, or CROs, that conduct our non-clinical studies and clinical trials;
- personnel costs, including salaries, related benefits and share-based compensation, for our employees engaged in scientific research and development functions;
- purchases, real-estate leasing costs, as well as conferences and travel costs; and
- depreciation, amortization and provisions.

Our direct research and development expenses consist principally of external costs, such as startup fees paid to investigators, consultants, central laboratories, and CROs in connection with our clinical trials, and costs related

---

[Table of Contents](#)

to acquiring and manufacturing clinical study materials. We do not allocate personnel-related costs, costs associated with our general platform improvements, depreciation or other indirect costs to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses.

Research and development activities are central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase in the foreseeable future as we initiate clinical trials for certain product candidates and pursue later stages of clinical development of our product candidates.

In the year ended December 31, 2022, we spent \$75.5 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, 2022 and 2021, respectively:

|   | Year Ended December 31,     |           |
|---|-----------------------------|-----------|
|   | 2022                        | 2021      |
|   | (thousands of U.S. Dollars) |           |
| Research and development expenses related to Viaskin Peanut (1)                                     | \$ 47,766                   | \$ 47,961 |
| As a percentage of research and development expenses,<br>excluding share-based compensation expense | 65%                         | 70%       |
| Research and development expenses related to Viaskin Milk (1)                                       | \$ 8,180                    | \$ 5,861  |
| As a percentage of research and development expenses<br>excluding share-based compensation expense  | 11%                         | 9%        |
| Other research and development expenses (1)   | \$ 17,295                   | \$ 14,868 |
| Total research and development expenses, excluding share-based<br>compensation expense              | \$ 73,241                   | \$ 68,690 |
| Share-based compensation expenses included in research and<br>development expenses                  | \$ 2,303                    | \$ 1,646  |
| Total research and development expenses   | \$ 75,543                   | \$ 70,336 |

(1) Excludes employee share-based compensation expense.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, many of which are outside of our control including:

- the FDA's approval of our BLA for Viaskin Peanut;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, especially in North America;
- the costs of securing manufacturing arrangements for commercial production;

---

**Table of Contents**

- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- 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 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.

A change in the outcome of any of these variables with respect to the development and commercialization of Viaskin Peanut, if approved, or any other product candidate that we are developing could mean a significant change in the costs and timing associated with the development and commercialization of Viaskin Peanut, if approved, or such other product candidate. For example, if the FDA or other regulatory authority were to require us to conduct pre-clinical and clinical trials beyond those which we currently anticipate will be required for the completion of clinical development, if we experience significant delays in enrollment in any clinical trials or if the FDA or other regulatory authority were to require us to conduct post-approval clinical trials, we could be required to spend significant additional financial resources and time on the completion of the clinical development and potential launch of commercialization.

**Components of Our Results of Operations****Operating Income**

Our operating income consists of other operating income, as described below, as we generated no revenue from our operating activities in 2022 or 2021.

**Other Operating Income****Government Assistance**

Due to the innovative nature of our product candidate development programs, we have benefited from a number of sources of assistance from the central French government or local public authorities, intended to finance our research and development efforts or the recruitment of specific personnel. These funds are recognized as other income in our consolidated statement of operations for the fiscal year that recorded the financed expenses or expenditures.

**Research Tax Credits**

The Research Tax Credit (*Crédit d'Impôt Recherche*, or CIR) 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 for the payment of the corporate 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.

---

**Table of Contents**

If a company meets certain criteria in terms of sales, headcount or assets to be considered a Small and Medium-sized Enterprises, or SMEs, under EU law, immediate payment of the CIR can be requested. We no longer benefited from the immediate reimbursement of the CIR due to the loss of the SME status under EU law for the fiscal year ending December 31, 2019 and 2020. The CIRs were to be refunded three years after the tax declaration in the event we could not offset it against corporate income tax due.

Beginning in the fiscal year ending December 31, 2021, we recovered our SME status, and became therefore eligible again for the immediate reimbursement of the CIR. During the fiscal year ending December 31, 2022, the Company received the reimbursement of the 2019, 2020 and 2021 fiscal year research tax credits for a total amount of \$26.1 million.

***Collaboration agreement with Nestlé Health Science***

On May 31, 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atop patch test tool for the diagnosis of cow's milk protein allergy in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a pivotal Phase 3 clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally, while prioritizing certain agreed-upon countries. We entered into an amendment with Nestlé Health Science on July 12, 2018. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016.

Our current clinical trials, including the Phase 2 clinical trial conducted as part of the development activities pursuant to the Development, Collaboration and License agreement with Nestlé Health Science, have been impacted by the Covid-19 pandemic, among other factors. We have experienced difficulties in enrolling new patients in this Phase 2 clinical trial notwithstanding the implementation of a protocol amendment and various other strategies to improve recruitment. As a result of the accumulation of recruitment delays, we expect to incur additional clinical and production costs related to the Phase 2 clinical trial as well as delays in achievement of upcoming milestones.

As of December 31, 2022, we recorded our collaboration agreement's revenue based on our updated measurement of progress of the Phase 2 clinical trial conducted as part of the agreement. The accrual recorded in the amount of the difference between our current best estimates of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 clinical trial has been updated accordingly. The revision of the estimated costs for the year ended December 31, 2022 was \$19.8 million compared to December 31, 2021, \$9.8 million.

***Operating Expenses***

Since inception, our operating expenses have consisted primarily of research and development activities, general and administration costs and sales and marketing costs.

***Research and Development Expenses***

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.

[Table of Contents](#)

Certain research and development projects are, or have been, partially funded by collaboration agreements, and the expenses related to these activities are included in research and development costs. The Company records the related reimbursement of research and development costs under these agreements as income in the period in which such costs are incurred.

**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, other consulting fees and travel costs. We anticipate that our sales and marketing expenses will increase 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.

**General and Administrative**

General and administrative expense consists primarily of personnel costs and share-based compensation for finance, legal, IT and administrative employees. General and administrative expense also consists of costs related to obtaining a directors and officers liability insurance policy and fees for professional services, mainly related to audit, tax and legal services, real-estate leasing costs, insurance costs, consulting costs, investor relations costs and corporate communication and travel costs.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research and development activities and the potential launch and commercialization of Viaskin Peanut in North America and in European Union, if approved. We also anticipate continued increased expenses associated with being a public company in the United States.

**Finance Income (Expense)**

Our cash and cash equivalents have been deposited primarily in savings and deposit accounts with a remaining maturity at the date of purchase of three months or less, allowing the funds to be freely withdrawn at any time without significant penalty. Savings and deposit accounts generate a limited amount of interest income, with very low counterparty risks. We expect to continue this investment strategy.

**Results of Operations**

*Comparison of the Years Ended December 31, 2022 and 2021*

The following table summarizes our results of 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, 2022 and 2021:

| (Dollar amounts presented in thousands, except per share amounts) | December 31,       |                    | \$ change    | % change     |
|---|--------------------|--------------------|--------------|--------------|
|   | 2022               | 2021               |              |              |
| <b>Operating income</b>   | <b>\$ 4,844</b>    | <b>\$ 5,708</b>    | <b>(864)</b> | <b>(15)%</b> |
| Operating expenses  |                    |                    |              |              |
| Research and development expenses                                 | (75,543)           | (70,336)           | (5,207)      | 7%           |
| Sales and marketing expenses                                      | (1,608)            | (4,387)            | 2,779        | (63%)        |
| General and administrative expenses                               | (24,324)           | (30,520)           | 6,196        | (20%)        |
| Restructuring income (expenses)                                   | —                  | 920                | (920)        | (100%)       |
| <b>Total Operating expenses</b>                                   | <b>(101,475)</b>   | <b>(104,323)</b>   | <b>2,848</b> | <b>(3%)</b>  |
| Financial income (expense)  | 427                | 425                | 2            | 1%           |
| Income tax  | (70)               | 381                | (451)        | (118%)       |
| <b>Net loss</b>   | <b>\$ (96,274)</b> | <b>\$ (97,809)</b> | <b>1,535</b> | <b>(32%)</b> |
| Basic/diluted Net loss per share attributable to shareholders     | (1.24)             | (1.78)             |              |              |

[Table of Contents](#)

*Operating Income*

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

| <i>(Dollar amounts presented in thousands)</i> | <b>December 31,</b> |              | <b>\$ change</b> | <b>% change</b> |
|--|---------------------|--------------|------------------|-----------------|
|  | <b>2022</b>         | <b>2021</b>  |                  |                 |
| Sales  | —                   | —            |                  |                 |
| Other income                                   | 4,844               | 5,708        | (864)            | (15)%           |
| Research tax credit                            | 5,718               | 7,505        | (588)            | (24)%           |
| Other operating (loss) income                  | (874)               | (1,797)      | 923              | (51)%           |
| <b>Total operating income</b>                  | <b>4,844</b>        | <b>5,708</b> | <b>(864)</b>     | <b>(15)%</b>    |

We generated operating income of \$4.8 million for the year ended December 31, 2022 compared to \$5.7 million for the year ended December 31, 2021, a decrease of 15%. The decrease in operating income is mainly attributable to the decrease in research tax credit eligible basis (studies ending in the course of 2022) and the change in the revenue recognized under the Nestle's collaboration agreement, as we updated the measurement of progress of the Phase 2 clinical trial conducted as part of the agreement due to delays in new patient enrollment. The decrease in research tax credit is attributable to the decline in eligible expenses in connection with research and development expenses.

*Operating Expenses*

*Research and Development Expenses*

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

| <i>(Dollar amounts presented in thousands)</i>            | <b>December 31,</b> |               | <b>\$ change</b> | <b>% change</b> |
|---|---------------------|---------------|------------------|-----------------|
|   | <b>2022</b>         | <b>2021</b>   |                  |                 |
| <b>Research and development expenses</b>                  |                     |               |                  |                 |
| External clinical-related expenses                        | 42,248              | 39,386        | 2,862            | 7%              |
| Employee-related costs excl. share-based payment expenses | 10,752              | 12,950        | (2,198)          | (17)%           |
| Share-based payment expenses                              | 2,303               | 1,646         | 656              | 40%             |
| Depreciation and amortization                             | 12,965              | 9,878         | 3,087            | 31%             |
| Other costs   | 7,276               | 6,476         | 800              | 12%             |
| <b>Total Research and development expenses</b>            | <b>75,543</b>       | <b>70,336</b> | <b>5,207</b>     | <b>7%</b>       |

Our research and development expenses consisted primarily of external costs, such as startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials, and costs related to acquiring and manufacturing clinical study materials.

Research and development expenses increased by \$5.2 million for the year ended December 31, 2022 compared to the year ended December 31, 2021.

External clinical-related expenses increased by \$2.9 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to upfront fees for the launch of Viaskin Peanut study for children ages 4-7 during the fourth quarter ended December 31, 2022.

Employee-related costs, excluding share-based payment expenses, decreased by \$2.2 million for the year ended December 31, 2022 compared to the year ended December 31, 2021 due to the workforce reduction following full implementation of the new organization.

[Table of Contents](#)

The increase in depreciation, amortization was primarily due to the increase of accrual recorded in the amount of the difference between our current best estimates of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 clinical trial conducted as part of the Nestlé agreement, partially offset by a decrease in tangible assets depreciation.

*Sales and Marketing Expenses*

The following table summarizes our sales and marketing expenses for the years presented:

| (Dollar amounts presented in thousands)                   | December 31, |              | \$ change      | % change     |
|---|--------------|--------------|----------------|--------------|
|   | 2022         | 2021         |                |              |
| <b>Sales and marketing expenses</b>                       |              |              |                |              |
| Employee-related costs incl. share-based payment expenses | 914          | 1,885        | (971)          | (52%)        |
| External professional services and other costs            | 694          | 2,502        | (1,808)        | (72%)        |
| <b>Total Sales and marketing expenses</b>                 | <b>1,608</b> | <b>4,387</b> | <b>(2,779)</b> | <b>(63%)</b> |

Sales and marketing expenses primarily included payroll for the U.S. employees as well as fees related to pre-commercialization activities for Viaskin Peanut in North America.

Sales and marketing expenses decreased by \$2.8 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to a decrease in employee-related costs, external professional services, and share-based payment expenses.

Employee-related costs (including share-based payments expenses) related to payroll for the U.S. employees, decreased by \$1.0 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to the workforce reduction we implemented as part of our 2020 global restructuring plan. The average workforce dedicated to sales and marketing decreased in comparison to 2021, from 4 employees to 2 employees in 2022.

External professional services and other costs decreased by \$1.8 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily as a result of budget discipline measures of pre-commercialization activities for Viaskin Peanut in North America.

*General and Administrative Expenses*

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

| (Dollar amounts presented in thousands)                   | December 31,  |               | \$ change      | % change     |
|---|---------------|---------------|----------------|--------------|
|   | 2022          | 2021          |                |              |
| <b>General and administrative expenses</b>                |               |               |                |              |
| External professional services fees                       | 5,947         | 7,944         | (1,997)        | (25%)        |
| Employee-related costs excl. share-based payment expenses | 7,320         | 8,194         | (874)          | (11%)        |
| Share-based payment expenses                              | 2,688         | 1,163         | 1,525          | 131%         |
| Depreciation, amortization and other costs                | 8,369         | 13,219        | (4,850)        | (37%)        |
| <b>Total General and administrative expenses</b>          | <b>24,324</b> | <b>30,520</b> | <b>(6,196)</b> | <b>(20%)</b> |

General and administrative expenses decreased by \$6.2 million for the year ended December 31, 2022 compared to the year ended December 31, 2021, primarily due to cost containment measures and decreased external professional fees (decreased by 2.0 million), partially offset by an increase in share-based payment expenses.

---

**Table of Contents**

The average workforce dedicated to general and administrative expenses decreased from 31 employees in 2021 to 27 employees in 2022.

Depreciation, amortization and other costs decreased by \$4.9 million mainly due to the decrease of insurance policies by \$2.7 million, mainly due to the decrease in Directors and Officers insurance premium.

*Financial income (loss)*

Our financial income was \$0.4 million in 2022 and 2021, and primarily includes the financial income on our financial assets and foreign exchange gains.

*Income tax*

Our income tax expense was \$70,000 for the year ended December 31, 2022, compared to a US Tax income of \$381,000 for the year ended December 31, 2021.

*Net loss*

Net loss was \$96.3 million for the year ended December 31, 2022, compared to \$97.8 million for the year ended December 31, 2021. Net loss per share (based on the weighted average number of shares outstanding over the period) was \$1.24 and \$1.78 for the year ended December 31, 2022 and 2021, respectively.

**Liquidity and Capital Resources**

**Financial Condition**

On December 31, 2022, we had \$209.2 million in cash and cash equivalents compared to \$77.3 million of cash and cash equivalents on December 31, 2021. We have incurred operating losses and negative cash flows from operations since our inception. Net cash used for operating activities was \$55.7 and \$108.2 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we recorded a net loss of \$96.3 million. Our net cash flows provided by financing activities totaled \$194.1 million in 2022, mainly consisting of our global offering in the second quarter of 2022.

**Sources of Liquidity and Material Cash Requirements**

Based on its current operations, plans and assumptions as revised pursuant to 2022 announcements related to EPITOPE Phase 3 study topline results and VITESSE Phase 3 partial clinical hold lift, as well as ATM and PIPE financings, the Company expects that its balance of cash and cash equivalents of \$209.2 million as of December 31, 2022 will be sufficient to fund its operations for at least the next 12 months.

We fund short-term cash requirements primarily from payments associated with research tax credits (*Crédit d'Impôt Recherche*).

In May 2022, we established an At-The-Market ("ATM") program to offer and sell, including with unsolicited investors who have expressed an interest, a total gross amount of up to \$100 million of American Depository Shares ("ADSs"), each ADS representing one-half of one ordinary share of the Company. The ATM program is intended to be effective through the expiration of the Company's existing registration statement registering the ADSs to be issued under the ATM program, i.e. until July 16, 2024, unless terminated prior to such date in accordance with the sales agreement or the maximum amount of the program has been reached. The Company intent is to use the net proceeds, if any, of sales of ADSs issued under the program, together with its existing cash and cash equivalents, primarily for activities associated with potential approval and launch of Viaskin Peanut, as well as to advance the development of the Company's product candidates using its Viaskin Platform and for working capital and other general corporate purposes.

[Table of Contents](#)

Pursuant to the ATM program, we issued and completed sales of new ordinary shares in form ADSs for a total gross amount of \$15.3 million (\$14.1 million net of transaction costs), each ADS representing one-half of one ordinary shares of the Company. The new ordinary shares were issued and delivered on May 6, 2022, and represent 10.96% of the existing shares already admitted to trading by this date.

In June 2022, we 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. Gross proceeds from PIPE financing total \$194 million (\$180.4 million net of transaction costs), before deducting private placement expenses.

During the years ended December 31, 2022 and 2021, we obtained the following financing on the public markets by issuance of securities, net of commissions and estimated offering expenses:

|  | <u>Equity capital</u> | <u>Bank Loans</u> | <u>Other debt</u> | <u>Total</u>   |
|--|-----------------------|-------------------|-------------------|----------------|
| (Amounts in thousands of U.S. Dollars) |                       |                   |                   |                |
| 2021                                   | —                     | —                 | —                 | —              |
| 2022                                   | 194,446               | —                 | —                 | 194,446        |
| <b>Total</b>                           | <b>194,446</b>        | —                 | —                 | <b>194,446</b> |

We have incurred net losses each year since our inception. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations. We have not incurred any bank debt.

We intend to seek 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 due to the ongoing COVID-19 pandemic and conflict in Ukraine. The ongoing COVID-19 pandemic and the conflict in Ukraine have already caused extreme volatility and disruptions in the capital and credit 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 are not successful in our financing objectives, we could have to scale back its operations, notably by delaying or reducing the scope of our research and development efforts or obtain financing through arrangements with collaborators or others that may require us to relinquish rights to our product candidates that we might otherwise seek to develop or commercialize independently.

The following table presents our material cash requirements for future periods:

|  | Material Cash Requirements Due by the Year Ended December 31, |               |              |            |
|--|---|---------------|--------------|------------|
|  | 2023  | 2024          | 2025         | Thereafter |
| Operating leases   | —   | —             | —            | —          |
| Purchase obligations—Obligations Under the Terms of CRO Agreements | 2,051   | 1,243         | 71           | —          |
| <b>Total</b>   | <b>23,336</b>   | <b>20,021</b> | <b>5,378</b> | <b>—</b>   |
|  | 25,387  | 21,264        | 5,449        | —          |
|  |   |               |              | 52,099     |

---

[Table of Contents](#)

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including interest on long-term debt, 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.

**Conditional advances**

In 2014, BpiFrance Finance granted an interest-free Innovation loan to DBV Technologies to help financing the pharmaceutical development of Viaskin™ Milk. This amount was received in a single disbursement on November 27, 2014. In 2020, due to the COVID-19 pandemic, Bpifrance postponed the repayments for a 6-month period. Repayment ended during the third quarter of 2022.

**Operating leases**

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,470 square meter facility, pursuant to a lease agreement dated March 3, 2015 and represents a \$3.4 million cash requirement as of December 31, 2022 which expires March 8, 2024.

Our primary U.S. office is located in Basking Ridge, New Jersey. In March 2022, we entered into a lease agreement, commencing on April 1, 2022 and effective for 38 months, for an office of 5,799 square feet in Basking Ridge, New Jersey. The Basking Ridge office represent a \$0.4 million cash requirement as of December 31, 2022 which expires June 1, 2025.

In light of the current stage of regulatory interactions regarding Viaskin Peanut, we are achieving the resizing of our facility use in North America that were initially intended to support our U.S. subsidiary as well as future commercialization needs:

- In January 2022, we entered into a termination agreement for our 21,548 square feet commercial facility in Summit, New Jersey. A one-time lump sum early termination fee of \$1.5 million was paid in 2022 and offset by the recognition of an income of \$1.2 million due to the early termination of this lease.
- In June 2021, we entered into a sublease agreement of our 3,780 square feet office space in Tower 49, New York, New York that both expire in the first quarter of 2023, simultaneously with the lease term.

**Purchase obligations—Obligations Under the Terms of CRO Agreements**

In connection with the launch of our clinical trials for Viaskin Peanut and Viaskin Milk, we signed agreements with several contract research organizations. As of December 31, 2022, expenses associated with the ongoing trials amounted globally to \$126.1 million, and we had non-cancellable contractual obligations with CRO until year ended 2025 amounting to \$48.7 million.

**Cash flows**

The table below summarizes our sources and uses of cash for the years ended December 31, 2022 and 2021.

|  | December 31,   | \$ change        | % change       |
|--|----------------|------------------|----------------|
|  | 2022           | 2021             |                |
| (Amounts in thousands of U.S. Dollars)                       |                |                  |                |
| Net cash flows used in operating activities                  | (55,666)       | (108,242)        | 52,576         |
| Net cash flows used in investing activities                  | (100)          | (433)            | 333            |
| Net cash flows provided by financing activities              | 194,120        | 274              | 193,846        |
| Effect of exchange rate changes on cash and cash equivalents | (6,461)        | (10,651)         | 4,190          |
| <b>Net (decrease) increase in cash and cash equivalents</b>  | <b>131,893</b> | <b>(119,051)</b> | <b>250,944</b> |

\* Percentage not meaningful

**Operating Activities**

Our net cash flows used in operating activities were \$55.7 million and \$108.2 million in 2022 and 2021 respectively. Our net cash flows used in operating activities decreased by \$52.6 million, or 49%, mainly due to the reclassification in 2021 (from non-current assets to current assets) of the 2019 to 2021 research tax credit that was fully reimbursed in 2022, and also due to cost containment measures and the decrease in personnel expenses related to the workforce reduction as part of our 2020 global restructuring plan.

**Investing Activities**

Our net cash flows used in investing activities were \$0.1 million and \$0.4 million in 2022 and 2021 respectively. Those investments in 2021 were mainly for our industrial machinery and equipment, which are commissioned in order to support the commercialization of Viaskin Peanut, if approved.

**Financing Activities**

Our net cash flows resulting from financing activities increased to \$194.1 million in 2022 from \$0.3 million in 2021. For the year ended December 31, 2022, financing activities are primarily composed of the net proceeds of our global offering in the second quarter of 2022.

Consistent with customary practice in the French securities market, we entered into a liquidity agreement (contrat de liquidité) with Natixis on April 13, 2012. The liquidity agreement complies with applicable laws and regulations in France. The liquidity agreement authorizes Natixis to carry out market purchases and sales of our shares on Euronext Paris. The amount is classified in other non-current financial assets in our Statement of financial position. At December 31, 2022, 149,793 shares and \$0.3 million were in the liquidity account. The liquidity agreement has a term of one year and will renew automatically unless otherwise terminated by either party.

**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 below. See Note 1 to our financial statements for a description of our other significant accounting policies.

**Revenue Recognition**—*Collaboration agreement with Nestlé Health Science*

On May 31, 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopatch test tool for the diagnosis of cow's milk protein allergy in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a pivotal Phase 3 clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally, while prioritizing certain agreed-upon countries. We entered into an amendment with Nestlé Health Science on July 12, 2018. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016.

Our current clinical trials, including the Phase 2 clinical trial conducted as part of the development activities pursuant to the Development, Collaboration and License agreement with Nestlé Health Science, have been impacted by the Covid-19 pandemic, among other factors. We have experienced difficulties in enrolling new patients in this Phase 2 clinical trial notwithstanding the implementation of a protocol amendment and various other strategies to improve recruitment. As a result of the accumulation of recruitment delays, we expect to incur additional clinical and production costs related to the Phase 2 clinical trial as well as delays in achievement of upcoming milestones.

As of December 31, 2022, we recorded our collaboration agreement's revenue based on our updated measurement of progress of the Phase 2 clinical trial conducted as part of the agreement. The accrual recorded in the amount of the difference between our current best estimates of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 clinical trial has been updated accordingly. The revision of the estimated costs for the year ended December 31, 2022 was \$19.8 million compared to December 31, 2021, \$9.8 million.

Our estimation of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 trial contains uncertainties because they require management to make assumptions and to apply judgment to estimate future cost and timeline for new patient enrollment in this PII. These estimates are subjective and our ability to achieve current best estimates is affected by factors such as ongoing COVID-19 pandemic and conflict in Ukraine.

**Share-Based Compensation**

We have various share-based compensation plans for employees and non-employees. We account for share-based compensation in accordance with the authoritative guidance on share-based compensation. Under the fair value recognition provisions of this guidance, share-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award.

Determining the fair value of the share-based payments at the grant date requires judgment. We calculated the fair value of stock options 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 our stock options 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 maturity of the share options.

---

[Table of Contents](#)*Expected term*

We determine the expected term based on the average period the stock options are expected to remain outstanding.

*Expected volatility*

We determine the expected volatility based on the historical data period corresponding to the stock options expected maturity.

*Expected dividend yield*

We have never declared or paid any cash dividends and we do not presently plan to pay cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero.

In the following table, the weighted average fair value of underlying shares are provided in euros, as we are incorporated in France and the euro is the currency used for the grants. We estimated the following assumptions for the calculation of the fair value of our stock options:

| Stock options per grant date                        | Assumptions<br>per year ended<br>December 31, |         |
|---|---|---------|
|   | 2022  | 2021    |
| Weighted average shares price at grant date (in €)  | 2.33  | 5.71    |
| Weighted average expected volatility                | 98.9%   | 90.2%   |
| Weighted average risk-free interest rate            | 2.2%  | (0.06)% |
| Weighted average expected term (in years)           | 6   | 6       |
| Dividend yield                                      | 0   | 0       |
| Weighted average fair value of stock-options (in €) | 2.23  | 4.17    |

\* The weighted average fair value of underlying shares is presented in euros, as we are incorporated in France and the euro is the currency used for the grants.

*Pre-funded warrants*

The Company has assessed the pre-funded warrants for appropriate equity or liability classification. During this assessment, the Company determined the pre-funded warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815.

The 2022 Warrants are classified as a component of permanent equity because they are 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 do not provide any guarantee of value or return.

Accordingly, the pre-funded warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance.

*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

---

[Table of Contents](#)

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**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

**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, 2022, 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

---

[Table of Contents](#)

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, 2022.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

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

Not applicable.

**PART III**

**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" and "Information About Our Executive Officers" in our Proxy Statement and is incorporated herein by reference.

**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 Proposal 5 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  | Incorporated by Reference |             |         |           |
|---------|--|---------------------------|-------------|---------|-----------|
|         |  | Schedule/Form             | File Number | Exhibit | File Date |
| 3.1*    | <a href="#">By-laws (statuts) of the registrant (English translation)</a>  |                           |             |         |           |
| 4.1     | <a href="#">Form of Deposit Agreement</a>  | Form F-1/A                | 333-198870  | 4.1     | 10/15/14  |
| 4.2     | <a href="#">Form of American Depository Receipt</a>  | Form F-1/A                | 333-198870  | 4.1     | 10/15/14  |
| 4.3     | <a href="#">Description of Registered Securities</a>   | Form 20-F                 | 001-36697   | 2.3     | 03/20/20  |
| 4.4     | <a href="#">Registration Rights Agreement, dated as of March 23, 2018, between the registrant, 667, L.P. and Baker Brothers Life Sciences, L.P.</a>  | Form 6-K                  | 001-36697   | 4.1     | 03/23/18  |
| 4.5     | <a href="#">Registration Rights Agreement, dated as of June 8, 2022, between the registrant and the Investors named therein.</a>   | Form 8-K                  | 001-36697   | 10.2    | 06/13/22  |
| 4.6     | <a href="#">Securities Purchase Agreement, dated as of June 8, 2022, between the registrant and the Subscribers named therein.</a>   | Form 8-K                  | 001-36697   | 10.1    | 06/13/22  |
| 10.1    | <a href="#">Office Lease between the registrant and GENERALI VIE, dated March 3, 2015 (English translation)</a>  | Form 20-F                 | 001-36697   | 4.2     | 04/29/15  |
| 10.2    | <a href="#">Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hôpitaux de Paris and Université Paris Descartes, dated January 7, 2009 (English translation)</a> | Form F-1                  | 333-198870  | 10.2    | 09/22/14  |
| 10.3#   | <a href="#">Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016</a>   | Form 20-F                 | 001-36697   | 4.14    | 03/22/17  |
| 10.4#   | <a href="#">Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 2018</a>   | Form 20-F                 | 001-36697   | 4.5     | 04/01/19  |
| 10.5†   | <a href="#">Form of Indemnification Agreement between the registrant and each of its executive officers and directors</a>  | Form F-1/A                | 333-198870  | 10.3    | 10/15/14  |
| 10.6†   | <a href="#">2013 and 2014 Share Option Plans (English translation)</a>   | Form F-1                  | 333-198870  | 10.4    | 09/22/14  |
| 10.7†   | <a href="#">2012, 2013 and 2014 Free Share Plans (English translation)</a>   | Form F-1                  | 333-198870  | 10.5    | 09/22/14  |
| 10.8†   | <a href="#">Summary of BSA</a>   | Form F-1                  | 333-198870  | 10.6    | 09/22/14  |
| 10.9†   | <a href="#">Summary of BSPCE</a>   | Form F-1                  | 333-198870  | 10.7    | 09/22/14  |
| 10.10†  | <a href="#">2015 Share Option Plan (English translation)</a>   | Form 20-F                 | 001-36697   | 4.10    | 04/28/16  |
| 10.11†  | <a href="#">2015 Free Share Plans (English translation)</a>  | Form 20-F                 | 001-36697   | 4.11    | 04/28/16  |

Table of Contents

| Exhibit | Description   | Incorporated by Reference |             |         |           |
|---------|---|---------------------------|-------------|---------|-----------|
|         |   | Schedule/Form             | File Number | Exhibit | File Date |
| 10.12†  | <a href="#">2016 Share Option Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.12    | 03/22/17  |
| 10.13†  | <a href="#">2016 Free Share Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.13    | 03/22/17  |
| 10.14†  | <a href="#">2017 Share Option Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.14    | 03/16/18  |
| 10.15†  | <a href="#">2017 Free Share Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.15    | 03/16/18  |
| 10.16†  | <a href="#">2018 Share Option Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.17    | 04/01/19  |
| 10.17†  | <a href="#">2018 Free Share Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.18    | 04/01/19  |
| 10.18†  | <a href="#">2019 Share Option Plan (English translation)</a>  | Form 20-F                 | 001-36697   | 4.19    | 03/20/20  |
| 10.19†  | <a href="#">2019 Free Share Plans (English translation)</a>   | Form 20-F                 | 001-36697   | 4.20    | 03/20/20  |
| 10.20†  | <a href="#">2020 Stock Option Plan (English translation)</a>  | Form 10-K                 | 001-36697   | 10.21   | 03/17/21  |
| 10.21†  | <a href="#">2020 Free Share Plan (English translation)</a>  | Form 10-K                 | 001-36697   | 10.22   | 03/17/21  |
| 10.22†  | <a href="#">2021 Stock Option Plan (English translation)</a>  | Form 10-K                 | 001-36697   | 10.22   | 03/9/22   |
| 10.23†  | <a href="#">2021 Free Share Plan (English translation)</a>  | Form 10-K                 | 001-36697   | 10.23   | 03/9/22   |
| 10.24†* | <a href="#">2022 Stock Option Plan (English translation)</a>  |                           |             |         |           |
| 10.25†* | <a href="#">2022 Free Share Plan (English translation)</a>  |                           |             |         |           |
| 10.26†  | <a href="#">Executive Agreement, dated November 29, 2018, between the registrant and Daniel Tassé</a>   | Form 10-K                 | 001-36697   | 10.23   | 03/17/21  |
| 10.27†  | <a href="#">First Amendment to the Executive Agreement of Daniel Tassé, dated June 27, 2019, between the registrant and Daniel Tassé</a>  | Form 10-K                 | 001-36697   | 10.24   | 03/17/21  |
| 10.28†  | <a href="#">Executive Agreement, dated July 22, 2019, between the registrant and Pharis Mohideen</a>  | Form 10-K                 | 001-36697   | 10.25   | 03/17/21  |
| 10.29†  | <a href="#">Letter Agreement, dated June 26, 2019, between the registrant and Sébastien Robitaille (English translation)</a>  | Form 10-K                 | 001-36697   | 10.26   | 03/17/21  |
| 10.30†  | <a href="#">Letter Agreement, dated December 1, 2020, between the registrant and Sébastien Robitaille (English translation)</a>   | Form 10-K                 | 001-36697   | 10.27   | 03/17/21  |
| 21.1    | <a href="#">List of subsidiaries of the registrant</a>  | Form 20-F                 | 001-36697   | 8.1     | 03/20/20  |
| 23.1*   | <a href="#">Consent of Deloitte &amp; Associés</a>  |                           |             |         |           |
| 23.2*   | <a href="#">Consent of KPMG S.A.</a>  |                           |             |         |           |
| 24.1*   | <a href="#">Power of Attorney (included on the signature page of this report)</a>   |                           |             |         |           |
| 31.1*   | <a href="#">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</a> |                           |             |         |           |

---

[Table of Contents](#)

| Exhibit  | Description   | Incorporated by Reference |             |         |           |
|----------|---|---------------------------|-------------|---------|-----------|
|          |   | Schedule/Form             | File Number | Exhibit | File Date |
| 31.2*    | <a href="#">Certification by 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</a>   |                           |             |         |           |
| 32.1**   | <a href="#">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</a> |                           |             |         |           |
| 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 2, 2023

Each person whose individual signature appears below hereby authorizes and appoints Daniel Tassé and Sébastien Robitaille, 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 2, 2023.

| <u>Signature</u>  | <u>Title</u>  |
|---|---|
| <i>/s/ Daniel Tassé</i><br>Daniel Tassé                     | Chief Executive Officer and Director<br>(Principal Executive Officer)   |
| <i>/s/ Sébastien Robitaille</i><br>Sébastien Robitaille     | Chief Financial Officer<br>(Principal Financial and Accounting Officer) |
| <i>/s/ Michel de Rosen</i><br>Michel de Rosen               | Director  |
| <i>/s/ Mailys Ferrere</i><br>Mailys Ferrere                 | Director  |
| <i>/s/ Michael J. Goller</i><br>Michael J. Goller           | Director  |
| <i>/s/ Danièle Guyot-Caparros</i><br>Danièle Guyot-Caparros | Director  |
| <i>/s/ Timothy E. Morris</i><br>Timothy E. Morris           | Director  |

---

[Table of Contents](#)

| <u>Signature</u>                         | <u>Title</u> |
|--|--------------|
| /s/ Adora Ndu<br>Adora Ndu               | Director     |
| /s/ Julie O'Neill<br>Julie O'Neill       | Director     |
| /s/ Ravi Madduri Rao<br>Ravi Madduri Rao | Director     |
| /s/ Daniel Soland<br>Daniel Soland       | Director     |

---

**Table of Contents**

| <b>Index to Financial Statements</b>  |             |
|---|-------------|
| <b><u>Annual Financial Statements for the Years Ended December 31, 2022 and 2021:</u></b>   |             |
|   | <b>Page</b> |
| <a href="#"><u>Report of Deloitte &amp; Associés and KPMG S.A., Independent Registered Public Accounting Firms (Deloitte &amp; Associés, Paris-La Défense, France, PCAOB ID No. 1756 ) (KPMG S.A., Paris-La Défense, France, PCAOB ID No. 1253)</u></a> | 2           |
| <a href="#"><u>Consolidated Statements of Financial Position as of December 31, 2022 and 2021</u></a>   | 5           |
| <a href="#"><u>Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2022 and 2021</u></a>  | 6           |
| <a href="#"><u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2022 and 2021</u></a>   | 7           |
| <a href="#"><u>Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2022 and 2021</u></a>  | 8           |
| <a href="#"><u>Notes to the Consolidated Financial Statements</u></a>   | 9           |

**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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, 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 Matters**

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (1) relate 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 critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

**Pre-funded warrants—Refer to Note 11 to the consolidated financial statements**

*Critical Audit Matter Description*

As described in Note 11 to the consolidated financial statements, the Company proceeded with a capital increase in cash with cancellation of preferential subscription rights reserved for categories of investors, an amount of €3,285,566.90, through the issuance of (i) 32,855,669 new ordinary shares at a price per ordinary share of €3.00 (corresponding to \$3.22) including a €2.90 share premium and (ii) prefunded warrants to purchase 28,276,331 new ordinary shares 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.

The Company determined that the pre-funded warrants are freestanding instruments that meet the criteria for classification as equity.

We identified the assessment of the accounting classification of the pre-funded warrants issued during the year as a critical audit matter. The accounting requirements related to the classification of financial instruments as debt or equity are complex. A slight variation in the interpretation of terms and conditions of the pre-funded warrants could result in the pre-funded warrants being classified as a liability, which would also impact the statement of operations, as the subsequent accounting for pre-funded warrants treated as liabilities is significantly different from those classified as equity. This matter required a high degree of auditor judgment to analyze the terms and conditions of the pre-funded warrants agreement to ensure management's interpretation of the relevant terms and conditions of the pre-funded warrants agreement led to an appropriate application of the accounting standards.

*How the Critical Audit Matter was Addressed in the Audit*

The audit procedure we performed to address this critical audit matter included the following: reading the pre-funded warrant agreement and the Company's analysis and comparing our interpretation of the terms and conditions of the warrant agreement with the analysis performed by management.

**Income and provision for loss at completion - Contract with Nestlé Health Science — Refer to Notes 13 and 14 to the consolidated financial statements**

*Critical Audit Matter Description*

As described further in Notes 13 and 14 to the consolidated financial statements, on May 31, 2016, the Company entered into an exclusive global collaboration agreement with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of cow's milk protein allergy in infants and toddlers. Under the terms of the exclusive collaboration, the Company is responsible for leading the development activities of MAG1C up through a pivotal Phase III clinical program.

As described in Note 1, the Company recognizes income under the percentage-of-completion method, and periodically updates its measurement of progress and its cumulative income accordingly. The Company uses

---

[Table of Contents](#)

costs incurred as the input method to determine progress. The Company accrues for any excess between costs yet to be incurred and income yet to be recognized for the completion of the performance obligations. As a consequence, the accounting for this contract involves estimates related to evaluation of costs to be incurred and the determination of the timeline for the Phase II clinical trial and Phase III clinical program.

As of December 31, 2022, the Company recorded its collaboration agreement's revenues based on its updated measurement of progress of the Phase II clinical trial conducted as part of the agreement. Given the Company has experienced difficulties in enrolling new patients in this Phase II clinical trial, the Company expects to incur additional clinical and production costs related to the Phase II clinical trial as well as delays in achievement of upcoming milestones. As a result, revenues were reversed for an amount of \$874 thousand and a loss provision of \$19,835 thousand was recorded for the year-then-ended.

We identified the evaluation of the costs to be incurred and estimated loss at completion for the collaboration agreement with Nestlé Health Science as a critical audit matter. Given estimates are necessary to determine total costs to complete for each clinical phase and milestone of the collaboration agreement, auditing such estimates required complex audit judgment to evaluate the estimated costs to achieve the performance obligations.

*How the Critical Audit Matter was Addressed in the Audit*

The primary audit procedures we performed to address this critical audit matter included the following:

- We compared the transaction prices to the consideration expected to be received based on the milestones defined within the collaboration agreement and any amendment or modification that were agreed to with Nestlé Health Science.
- For a selection of transactions, we tested the accuracy of costs actually incurred for the collaboration agreement in the current year by agreeing the amounts to invoices.
- We evaluated the estimate of total costs to be incurred by:
  - Evaluating the global timeline of the clinical study defined by management as part of their budget process to assess if it is consistent with the external assumptions from the Contract Research Organization (CRO) as related to the recruitment of patients.
  - Evaluating the estimates prepared by management to assess if they are consistent with the approved cash trajectory and budget approved by the Company's Board of Directors.
  - Performing a look-back analysis by comparing prior year costs to be incurred estimated by management to the actual prior year costs recorded by the Company to identify potential management bias.
  - Evaluating management's ability to achieve the estimate of total costs and profit or loss by performing inquiries with the Company's project manager.

/s/ Deloitte & Associés

KPMG S.A.

/s/ Cédric Adens

Partner

We have served as the Company's auditor since 2011.

Paris-La Défense, France  
March 2, 2023

F- 4

| DBV Technologies S.A.<br>Consolidated Statements of Financial Position<br>(amounts in thousands, except share and per share data)         |      |                         |                   |
|---|------|-------------------------|-------------------|
|   | Note | Year ended December 31, |                   |
|   |      | 2022                    | 2021              |
| <b>Assets</b>   |      |                         |                   |
| Current assets:   |      |                         |                   |
| Cash and cash equivalents   | 3    | \$ 209,194              | \$ 77,301         |
| Trade receivables   | 4    | —                       | —                 |
| Other current assets  | 5    | 13,880                  | 37,085            |
| <b>Total current assets</b>   |      | <b>223,074</b>          | <b>114,386</b>    |
| Property, plant, and equipment, net   | 6    | 15,096                  | 18,146            |
| Right-of-use assets related to operating leases   | 7    | 2,513                   | 7,336             |
| Intangible assets   | 8    | 10                      | 22                |
| Other non-current assets  | 9    | 5,824                   | 6,833             |
| <b>Total non-current assets</b>   |      | <b>23,444</b>           | <b>32,338</b>     |
| <b>Total Assets</b>   |      | <b>\$ 246,518</b>       | <b>\$ 146,723</b> |
| <b>Liabilities and shareholders' equity</b>   |      |                         |                   |
| Current liabilities:  |      |                         |                   |
| Trade payables  | 10   | \$ 14,473               | \$ 11,429         |
| Short-term operating leases   | 11   | 1,894                   | 3,003             |
| Short-term financial debt   | 12   | —                       | 510               |
| Current contingencies   | 13   | 3,944                   | 4,095             |
| Other current liabilities   | 14   | 9,210                   | 12,361            |
| <b>Total current liabilities</b>  |      | <b>29,521</b>           | <b>31,397</b>     |
| Long-term operating leases  | 15   | 1,127                   | 7,147             |
| Long-term financial debt  |      | —                       | —                 |
| Non-current contingencies   | 16   | 16,680                  | 6,758             |
| Other non-current liabilities   | 17   | 4,735                   | 2,147             |
| <b>Total non-current liabilities</b>  |      | <b>22,543</b>           | <b>16,052</b>     |
| <b>Total liabilities</b>  |      | <b>\$ 52,064</b>        | <b>\$ 47,449</b>  |
| Shareholders' equity:   |      |                         |                   |
| Ordinary shares, € 0.10 par value; 94,137,145 and 55,095,762 shares authorized, and issued as at December 31, 2022 and 2021, respectively |      | \$ 10,720               | \$ 6,538          |
| Additional paid-in capital  |      | 458,221                 | 358,115           |
| Treasury stock, 149,793 and 153,631 ordinary shares as of December 31, 2022 and 2021, respectively, at cost                               |      | (1,109)                 | (1,232)           |
| Accumulated deficit   |      | (259,578)               | (258,528)         |
| Accumulated other comprehensive income  |      | 781                     | 519               |
| Accumulated currency translation effect   |      | (14,581)                | (6,137)           |
| <b>Total shareholders' equity</b>   | 18   | <b>\$ 194,453</b>       | <b>\$ 99,274</b>  |
| <b>Total liabilities and shareholders' equity</b>   |      | <b>\$ 246,518</b>       | <b>\$ 146,723</b> |

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)                            |      |                         |                      |
|  | Note | Year ended December 31, |                      |
|  | 14   | 2022                    | 2021                 |
| <b>Operating income</b>  |      | <b>\$ 4,844</b>         | <b>\$ 5,708</b>      |
| <b>Operating expenses</b>  |      |                         |                      |
| Research and development expenses  | 15   | ( 75,543)               | ( 70,336)            |
| Sales & marketing expenses   | 15   | ( 1,608)                | ( 4,387)             |
| General & administrative expenses  | 15   | ( 24,324)               | ( 30,520)            |
| Restructuring reversal (expenses)  | 15   | 920                     |                      |
| <b>Total Operating expenses</b>  |      | <b>( 101,475)</b>       | <b>( 104,323)</b>    |
| <b>Loss from operations</b>  |      | <b>( 96,631)</b>        | <b>( 98,614)</b>     |
| Financial income (expenses)  |      | 427                     | 425                  |
| <b>Loss before taxes</b>   |      | <b>( 96,204)</b>        | <b>( 98,189)</b>     |
| Income tax   | 16   | ( 70)                   | 381                  |
| <b>Net loss</b>  |      | <b>\$ ( 96,274)</b>     | <b>\$ ( 97,809)</b>  |
| Foreign currency translation differences, net of taxes                             |      | ( 8,420)                | ( 12,296)            |
| Actuarial gains on employee benefits, net of taxes                                 |      | 262                     | 35                   |
| <b>Total comprehensive loss</b>  |      | <b>\$ ( 104,441)</b>    | <b>\$ ( 110,070)</b> |
| Basic/diluted Net loss per share attributable to shareholders                      | 19   | \$ ( 1.24)              | \$ ( 1.78)           |
| Weighted average number of shares outstanding used in computing per share amounts: | 19   | 77,384,133              | 54,916,937           |

The accompanying notes are an integral part of these consolidated financial statements

| DBV Technologies S.A.<br>Consolidated Statements of Cash Flows<br>(amounts in thousands) |                            |                   |  |
|--|----------------------------|-------------------|--|
| Notes  | Year ended December 31,    |                   |  |
|  | 2022                       | 2021              |  |
| <b>Net loss for the period</b>   | \$ 96,274                  | \$ ( 97,809)      |  |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b>       |                            |                   |  |
| Depreciation, amortization and accrued contingencies                                     | 13,162                     | 8,376             |  |
| Retirement pension obligations   | 105                        | 184               |  |
| Expenses related to share-based payments   | 5,026                      | 3,122             |  |
| Other elements   | ( 7)                       | 656               |  |
| <b>Changes in operating assets and liabilities:</b>                                      |                            |                   |  |
| Decrease (increase) in inventories and work in progress                                  | —                          | —                 |  |
| Decrease (increase) in trade receivables   | —                          | 2,150             |  |
| Decrease (increase) in other current assets  | 20,961                     | ( 8,578)          |  |
| (Decrease) increase in trade payables  | 3,456                      | ( 7,559)          |  |
| (Decrease) increase in other current and non-current liabilities                         | 152                        | ( 7,599)          |  |
| Change in operating lease liabilities and right of use assets                            | ( 2,249)                   | ( 1,185)          |  |
| <b>Net cash flow used in operating activities</b>  | <u>55,666</u>              | <u>( 108,242)</u> |  |
| <b>Cash flows used in investing activities:</b>  |                            |                   |  |
| Acquisitions of property, plant, and equipment   | ( 754)                     | ( 910)            |  |
| Proceeds from property, plant, and equipment dispositions                                | 8                          | 604               |  |
| Acquisitions of intangible assets  | —                          | ( 8)              |  |
| Acquisitions of non-current financial assets   | ( 123)                     | ( 119)            |  |
| Proceeds from non-current financial assets dispositions                                  | 770                        | —                 |  |
| <b>Net cash flows used in investing activities</b>                                       | <u>( 100)</u>              | <u>( 433)</u>     |  |
| <b>Cash flows provided by financing activities:</b>                                      |                            |                   |  |
| (Decrease) increase in conditional advances  | ( 474)                     | ( 689)            |  |
| Treasury shares  | 123                        | 184               |  |
| Capital increases, net of transaction costs  | 194,471                    | 794               |  |
| Other cash flows related to financing activities   | —                          | ( 15)             |  |
| <b>Net cash flows provided by financing activities</b>                                   | <u>194,120</u>             | <u>274</u>        |  |
| Effect of exchange rate changes on cash and cash equivalents                             | ( 6,461)                   | ( 10,651)         |  |
| <b>Net (decrease) / increase in cash and cash equivalents</b>                            | <u>131,893</u>             | <u>( 119,051)</u> |  |
| Net cash and cash equivalents at the beginning of the period                             | 77,301                     | 196,352           |  |
| <b>Net cash and cash equivalents at the end of the period</b>                            | <u>3</u> <u>\$ 209,194</u> | <u>\$ 77,301</u>  |  |

The accompanying notes are an integral part of these consolidated financial statements

| DBV Technologies S.A.<br>Consolidated Statements of Changes in Shareholders' Equity<br>(amounts in thousands, except share and per share data) |                                |                  |                                  |                   |                     |  |   |                   |
|--|--------------------------------|------------------|----------------------------------|-------------------|---------------------|--|---|-------------------|
|  | Number of<br>Shares<br>Note 12 | Amount           | Additional<br>paid-in<br>capital | Treasury<br>stock | Acc.<br>deficit     | Acc.<br>other<br>comprehensive<br>income | Acc.<br>currency<br>translation<br>effect | Total<br>Equity   |
| <b>Balance at January 1, 2021</b>  | <b>54,929,187</b>              | <b>\$ 6,518</b>  | <b>\$ 1,152,042</b>              | <b>\$ (1,169)</b> | <b>\$ (958,543)</b> | <b>\$ 484</b>                            | <b>\$ 6,315</b>                           | <b>\$ 205,491</b> |
| Net (loss)   |                                |                  |                                  |                   | (97,809)            |  |   | (97,809)          |
| Other comprehensive (loss)   |                                |                  |                                  |                   |                     | 35                                       | (12,296)                                  | (12,296)          |
| Issuance of ordinary shares  | 166,575                        | 20               | 496                              |                   |                     |  | 515                                       | 515               |
| Issuance of share warrants   | —                              | —                | 279                              |                   | (63)                |  | 279                                       | 279               |
| Treasury shares  |                                |                  |                                  |                   |                     |  | (63)                                      | (63)              |
| Share-based payments (income) expenses   |                                | 3,122            |                                  |                   |                     |  | 3,122                                     | 3,122             |
| Allocation of accumulated net losses   |                                |                  | (797,823)                        |                   | 797,823             |  |   |                   |
| <b>Balance at December 31, 2021</b>  | <b>55,095,762</b>              | <b>\$ 6,538</b>  | <b>\$ 358,115</b>                | <b>\$ (1,232)</b> | <b>\$ (258,528)</b> | <b>\$ 519</b>                            | <b>\$ (6,437)</b>                         | <b>\$ 99,274</b>  |
| Net (loss)   |                                |                  |                                  |                   | (96,274)            |  |   | (96,274)          |
| Other comprehensive (loss)   |                                |                  |                                  |                   |                     | 262                                      | (8,429)                                   | (8,429)           |
| Issuance of ordinary shares  | 39,041,383                     | 4,182            | 102,194                          |                   |                     |  | 106,377                                   | 106,377           |
| Issuance of share warrants   | —                              | —                | 88,094                           |                   |                     |  | 88,094                                    | 88,094            |
| Treasury shares  |                                |                  |                                  |                   | 123                 |  |   | 123               |
| Share-based payments (income) expenses   |                                | 5,026            |                                  |                   |                     |  | 5,026                                     | 5,026             |
| Allocation of accumulated net losses   |                                |                  | (95,209)                         |                   | 95,209              |  |   |                   |
| Other change in equity   |                                |                  |                                  |                   |                     | 15                                       |   | (15)              |
| <b>Balance at December 31, 2022</b>  | <b>94,137,145</b>              | <b>\$ 10,720</b> | <b>\$ 458,221</b>                | <b>\$ (1,109)</b> | <b>\$ (259,578)</b> | <b>\$ 781</b>                            | <b>\$ (14,581)</b>                        | <b>\$ 194,453</b> |

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 clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Vlaskin™. The Company's therapeutic approach is based on epicutaneous immunotherapy, or EPIT™, a proprietary method of delivering biologically active compounds to the immune system through intact skin using Vlaskin™.

**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.

**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, 2021 and 2022, 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 "US subsidiary"). The share capital of this US 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 Technologies").
- DBV Pharma was incorporated in Paris on December 21, 2018 (the "French subsidiary"). The share capital of this French subsidiary is 100 % owned by DBV Technologies S.A.

On December 31, 2021, the company proceeded to the dissolution of DBV Canada Ltd. This subsidiary was originally incorporated in Ottawa, Ontario on August 13, 2018 (the "Canadian subsidiary"). The share capital of this Canadian subsidiary was 100 % owned by DBV Technologies S.A.

**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 entity individual statements of operations in "Financial income (expense)": they will be recognized in profit or loss on disposal of the net investment.

**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 Company bases its estimates and assumptions on historical experience and other factors that it believes to be reasonable under the circumstances.

As of December 31, 2022, the ongoing pandemic may make management's estimates vulnerable to significant changes. Those uncertainties were considered in the assumptions underlying the estimates and judgments used by the Company but a number of estimates have been and will continue to be affected by the ongoing pandemic. The Company evaluates its estimates and assumptions on an ongoing basis. The actual results may differ from these estimates.

On an on-going basis, management evaluates its estimates, primarily those related to: (1) evaluation of costs and measure of progress of the development activities conducted as part of the collaboration agreement with Nestlé Health Science, (2) research tax credits, (3) assumptions used in the valuation of right-of-use assets—operating lease, (4) impairment of right-of-use assets related to leases and property, plant and equipment, (5) recoverability of the Company's net deferred tax assets and related valuation allowance, (6) assumptions used in the valuation model to determine the fair value and vesting conditions of share-based compensation plan, and (7) estimate of contingencies.

**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.

Since its inception, the Company has primarily funded its 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). The Company does not generate product revenue and continues to prepare for the potential launch of its first product in the United States and in the European Union, if approved.

Following receipt of a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") in connection with its BLA for Viaskin™ Peanut, in August 2020, the Company scaled down its other clinical programs and pre-clinical spend to focus on Viaskin™ Peanut. The Company also initiated a global restructuring plan in June 2020 to provide operational latitude to progress the clinical development and regulatory review of Viaskin™ Peanut in the United States and European Union.

In January 2021, the Company received written responses from the FDA to questions provided in the Type A meeting request the Company submitted in October 2020 following the CRL. In order to respond to the FDA's requests and recommendations, the Company defined parallel workstreams primarily in order to generate the 6-month safety and adhesion clinical data to assess a modified Viaskin Peanut patch and demonstrate the equivalence in allergen uptake between the current and modified patches in the intended patient population.

---

[Table of Contents](#)

Following the submission of the adhesion study's protocol to the FDA, the Company received an Advice/Information Request letter from the FDA in October 2021, requesting a stepwise approach to the modified Viaskin patch development program and provided partial feedback on this protocol.

In December 2021, the Company decided not to pursue the sequential approach to the development plans for Viaskin Peanut as requested by the FDA in the October 2021 feedback and announced its plan to initiate a pivotal Phase 3 clinical study for a modified Viaskin Peanut patch (mVP) in children in the intended patient population. The Company considers this approach as the most straightforward approach to demonstrate effectiveness, safety, and improved in vivo adhesion of the modified Viaskin Peanut system. After receiving approval from the FDA for its change in strategy, the protocol for the new Phase 3 pivotal study of the modified Viaskin Peanut ("mVP") patch was completed at the end of February 2022 and has been prepared for FDA submission.

In May 2022, the Company established an At-The-Market ("ATM") program allowing to offer and sell, including with unsolicited investors who have expressed an interest, a total gross amount of up to \$ 100 million of American Depository Shares ("ADSs"). The Company's intent is to use the net proceeds, if any, of sales of ADSs issued under the program, together with its existing cash and cash equivalents, primarily for activities associated with potential approval and launch of Viaskin Peanut, as well as to advance the development of the Company's product candidates using its Viaskin Platform and for working capital and other general corporate purposes.

In June 2022, the Company announced that its pivotal Phase 3 trial EPITOPE, assessing the safety and efficacy of Viaskin Peanut treatment of peanut-allergic toddlers ages 1 to 3 years, met its primary endpoint, with a statistically significant treatment effect. The Company also indicated continuing productive dialogue with the FDA on the protocol design of VITESSE, a pivotal Phase 3 trial of the modified Viaskin Peanut patch in peanut-allergic children ages 4 to 7 years.

During the same month, the Company announced private placement financing ("PIPE") amounting to \$ 194 million.

In September 2022, after announcing initiating, the Company received a partial clinical hold letter from the FDA on its VITESSE Phase 3 clinical study. Within the FDA's communication, the modifications address design elements, including the statistical analysis of adhesion, minimum daily wear time and technical alignments in methods of categorizing data, to meet study objectives as well as the total number of trial participants on active treatment.

In December 2022, the Company received confirmation from the FDA that it lifted the partial clinical hold on its VITESSE Phase 3 clinical study. The Company indicated the updated protocol will be submitted to study sites for subsequent Institutional Review Boards and Ethics Committees approval.

Based on its current operations, plans and assumptions as revised pursuant to 2022 announcements related to EPITOPE Phase 3 study topline results and VITESSE Phase 3 partial clinical hold lift, as well as ATM and PIPE financings, the Company expects that its balance of cash and cash equivalents of \$ 209.2 million as of December 31, 2022 will be sufficient to fund its operations for at least the next 12 months.

The Company intends to seek additional capital as it prepares for the launch of Viaskin Peanut, if approved, and continues other research and development efforts. The Company may seek to finance its 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.

The Company cannot guarantee that it will be able to obtain the necessary financing to meet its needs or to obtain funds at attractive terms and conditions, including as a result of disruptions to the global financial markets due to the ongoing COVID-19 pandemic and conflict in Ukraine. The ongoing COVID-19 pandemic and conflict in Ukraine have already caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to the Company, including reduced ability to raise additional capital when needed or on acceptable terms, if at all.

---

[Table of Contents](#)

If the Company is not successful in its financing objectives, the Company could have to scale back its operations, notably by delaying or reducing the scope of its research and development efforts or obtain financing through arrangements with collaborators or others that may require the Company to relinquish rights to its product candidates that the Company might otherwise seek to develop or commercialize independently.

These Consolidated Financial Statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

**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.

**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.

**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.

F-1 2

---

[Table of Contents](#)

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.

**Inventories and Work in Progress**

Inventories are measured at the lower of cost or net realizable value at production costs calculated using the first-in, first-out method. It includes acquisition costs, processing costs and other costs incurred in bringing the inventories to their present location and condition.

Inventories are exclusively composed of work in progress relating to the production of the first batches that may be used for the commercialization.

During the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval.

**Financial Assets and Liabilities**

Financial assets, excluding cash and cash equivalents, consist exclusively of other receivables. Other receivables are non-derivative financial assets with a payment, which is fixed or can be determined, not listed on an active market. They are included in current assets, except those that mature more than twelve months after the reporting date. The recoverable amount of other receivables is estimated whenever there is an indication that the asset may be impaired and at least on each reporting date. If the recoverable amount is lower than the carrying amount, an impairment loss is recognized in the Consolidated Statements of Operations and Comprehensive Loss.

The Company also receives from time-to-time assistance in the form of conditional advances, which are advances repayable in whole or in part based upon acknowledgment by the funder of a technical or commercial success of the related project by the funding entity.

The amount resulting from the deemed benefit of the interest-free nature of the award is considered a subsidy for accounting purposes. This deemed benefit is determined by applying a discount rate equal to the rate of fungible treasury bonds over the time period that corresponds to the time period of the repayment of the advances.

In the event of a change in payment schedule of the stipulated repayments of the conditional advances, the Company makes a new calculation of the net book value of the debt resulting from the discounting of the expected new future cash flows. The adjustment that results therefrom is recognized in the income statement for the fiscal year during which the modification is recognized.

F-1 3

---

[Table of Contents](#)

The Company carries its trade receivable at net realizable value. On a periodic basis, the Company evaluates its trade receivable and determines whether to provide an allowance or if any accounts should be written down and charged to expense as a bad debt. The Company generally does not require any security or collateral to support its receivables.

During the years ended December 31, 2022 and December 31, 2021, the Company did not hold any derivative financial instruments.

#### **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.

The Company considers its cash and cash equivalents, accounts receivable and accounts payable to reflect their fair value given their short maturity and risk profile of the counterparty.

#### **Cash and Cash Equivalents**

Cash includes cash on hand and demand deposits with banks. Cash equivalents include short-term, highly liquid investments, with a remaining maturity at the date of purchase of three months or less 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.

#### **Concentration of Credit Risk**

The Company has no significant off-balance sheet risk, such as foreign currency contracts, options contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and other receivables. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships or entities for which it has a receivable.

**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.

**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.

**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.

**Operating Income**

The Company accounts for revenue when the amount can be reliably assessed, future economic benefits are likely to benefit the Company, and specific criteria are met for the Company's business, which is in accordance with ASC 606 for the collaboration agreement with Nestlé Health Science.

***Other operating income***

***Research Tax Credit***

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, or SMEs, status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit. During the year ended December 31, 2022, the Company received the reimbursement of \$ 26.1 million of the 2019, 2020 and 2021 fiscal year research tax credit.

***Collaboration agreement with Nestlé Health Science***

The Company entered into research and development collaboration agreements that may consist of non-refundable upfront payments and milestone payments.

Non-refundable upfront payments are deferred and recognized as income over the period of the collaboration agreement.

Milestone payments represent amounts received depending upon the achievement of certain scientific, regulatory, or commercial milestones. They are recognized when the triggering event has occurred, there are no further contingencies or services to be provided with respect to that event, and the co-contracting party has no right to require refund of payment. The triggering event may be scientific results achieved by the Company or another party to the arrangement, regulatory approvals, or the marketing of products developed under the arrangement.

The Company recognizes income under the percentage-of-completion method, using costs incurred as the input method to determine progress towards the achievement of each milestone, and recognizing revenue based on costs incurred to date plus the estimate of margin at completion of the milestone. The Company periodically updates its measurement of progress and updates its cumulative income recognized accordingly. The Company accrues for any excess between costs yet to be incurred and income yet to be recognized for the completion of the performance obligations. Please refer to Note 13 "Contingencies".

***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.

Certain research and development projects are, or have been, partially funded by collaboration agreements, and the expenses related to these activities are included in research and development costs. The Company records the related reimbursement of research and development costs under these agreements as income in the period in which such costs are incurred. Please refer to Collaboration agreement with Nestlé Health Science for further detail.

**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.

These awards are measured at their fair value on the date of grant. Except for RSUs, fair value is estimated using Black and Scholes models that require inputs based on certain subjective assumptions, including the expected term of the award, and the conditions of each equity plan. 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 period, and such expense is reduced for estimated forfeitures, with a corresponding increase in shareholders' equity.

The determination of the requisite service period and the estimate of RSUs awards that are expected to vest depends 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 the accounting for the share-based payments.

At each closing date, the Company re-assesses 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.

**Income Tax**

Income taxes are accounted for under the asset and liability method of accounting. 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.

**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, 2022 and 2021, 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 March 2, 2023, the date at which the consolidated financial statements are issued.

**Accounting Pronouncements adopted in 2022**

The Company has not adopted any new accounting pronouncements in 2022 to date.

**Accounting Pronouncements issued not yet adopted**

In June 2016, the FASB issued ASU 2016-13—Financial Instruments—Credit losses, which replaces the incurred loss impairment methodology for financial instruments in current U.S. GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The FASB has issued ASU 2019-10 which has resulted in the postponement of the effective date of the new guidance for eligible smaller reporting companies to the fiscal year beginning January 1, 2023. The guidance must be adopted using a modified-retrospective approach and a prospective transition approach is required for debt securities for which an other-than-temporary impairment had been recognized before the effective date. The Company is currently evaluating the impact of the guidance on its Consolidated Financial Statements. The Company does not expect that this new standard will have a material impact on its consolidated financial statements.

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.

**Note 2 Significant Events and Transactions of the Periods**

**Clinical programs**

United States Regulatory History and Current Status

In January 2021, the Company received written responses from the FDA to questions provided in the Type A meeting request the Company submitted in October 2020 following the CRL. The FDA agreed with its position that a modified Viaskin Peanut patch should not be considered as a new product entity provided the occlusion chamber of the current Viaskin Peanut patch and the peanut protein dose of 250 µg (approximately 1/1,000 of one peanut) remains unchanged and performs in the same way it has performed previously. In order to confirm the consistency of efficacy data between the existing and a modified patch, FDA requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4 - 11. The Company named that assessment EQUAL, which stands for Equivalence in Uptake of Allergen. The FDA also recommended conducting a 6-month, well-controlled safety and adhesion trial to assess Safety, Tolerability, and Adhesion of Modified Patches.

Based on the January 2021 FDA feedback, the Company defined three parallel workstreams:

1. Identify a modified Viaskin patch (which the Company calls mVP).
2. Generate the 6-month safety and adhesion clinical data FDA requested via STAMP, which the Company expected to be the longest component of the mVP clinical plan. The Company prioritized the STAMP protocol submission so the Company could begin the clinical trial as soon as possible.
3. Demonstrate the equivalence in allergen uptake between the current and modified patches in the intended patient population via EQUAL. The complexity of EQUAL hinged on the lack of established clinical and regulatory criteria to characterize allergen uptake via an epicutaneous patch. To support those exchanges, the Company outlined its proposed approach to demonstrate allergen uptake equivalence between the two patches, and allotted time to generate informative data through two additional Phase 1 clinical trials in healthy adult volunteers:
  - a. PREQUAL, a Phase 1 trial with adult healthy volunteers to optimize the allergen sample collection methodologies and validate the assays we intend to use in EQUAL. The data collection phase of the trial is complete, and the data analysis phase is ongoing.
  - b. 'EQUAL in adults'—a second Phase 1 trial with adult healthy volunteers to compare the allergen uptake of cVP and mVP.

In March 2021, the Company commenced CHAMP (Comparison of adHesion Among Modified Patches), a Phase 1 trial in healthy adult volunteers to evaluate the adhesion of five modified Viaskin Peanut patches. The Company completed CHAMP in the second quarter of 2021. All modified Viaskin Peanut patches demonstrated better adhesion performance as compared to the then-current Viaskin Peanut patch, and based on the results of CHAMP, the Company then selected two modified patches that performed best out of the five modified patches studied for further development. The Company then selected the circular patch for further development, which is approximately 50% larger in size relative to the current patch and circular in shape.

In May 2021, the Company submitted its proposed STAMP protocol to the FDA, and on October 14, 2021, the Company received an Advice/Information Request letter from the FDA. In this letter, the FDA requested a stepwise approach to the modified Viaskin patch development program and provided partial feedback on the STAMP protocol. Specifically, the FDA requested that the Company conducts allergen uptake comparison trials (i.e., 'EQUAL in Adults', EQUAL), and submits the allergen uptake comparison data for FDA review and feedback prior to starting the STAMP study. The FDA's explanation was that the results from the allergen uptake studies might affect the design of the STAMP study.

---

**Table of Contents**

After careful review of the FDA's information requests, in December 2021, the Company decided not to pursue the sequential approach to the development plans for Viaskin Peanut as requested by the FDA in the October 2021 feedback. The Company estimated that the FDA's newly proposed sequential approach would require at least five rounds of exchanges that necessitate FDA alignment prior to initiating STAMP, the 6-month safety and adhesion study. As such, in December 2021, the Company announced its plan to initiate a pivotal Phase 3 placebo-controlled efficacy trial for a modified Viaskin Peanut patch (mVP) in children in the intended patient population. The Company considers this approach the most straightforward to potentially demonstrate effectiveness, safety, and improved *in vivo* adhesion of the modified Viaskin Peanut system. The FDA confirmed the Company's change in strategy was agreeable via oral and written exchanges.

In 2022, the Company announced the new Phase 3 pivotal study of the modified Viaskin Peanut (mVP) patch would be in younger (4-7 years old) and more sensitive children with peanut allergy.

***European Union Regulatory History and Current Status***

On August 2, 2021, the Company announced it has received from the EMA the Day 180 list of outstanding issues, which is an established part of the prescribed EMA review process. It is a letter that is meant to include any remaining questions or objections at that stage in the process. The EMA indicated many of their objections and major objections from the Day 120 list of questions had been answered. One major objection remained at Day 180. The Major Objection questioned the limitations of the data, for example, the clinical relevance and effect size supported by a single pivotal study.

On December 20, 2021, the Company announced it has withdrawn the MAA for Viaskin Peanut and formally notified the EMA of our decision. The initial filing was supported by data from a single, placebo-controlled Phase 3 pivotal trial known as PEPITES (V712-301). The decision to withdraw was based on the view of CHMP that the data available to date from a single pivotal clinical trial were not sufficient to preclude a Major Objection at Day 180 in the review cycle. The Company believe data from a second Viaskin Peanut pivotal clinical trial will support a more robust path for licensure of Viaskin Peanut in the EU. The Company intend to resubmit the MAA when that data set is available.

***Viaskin Peanut for Children ages 1-3***

In June 2020, the Company announced that in Part A, patients in both treatment arms showed consistent treatment effect after 12 months of therapy, as assessed by a double-blind placebo-controlled food challenge and biomarker results. Part A subjects were not included in Part B and the efficacy analyses from Part A were not statistically powered to demonstrate superiority of either dose versus placebo. These results validate the ongoing investigation of the 250 µg dose in this age group, which is the dose being studied in Part B of the study. Enrollment of Part B of EPITOPE was complete in first quarter of 2021.

In June 2022, we announced positive topline results from Part B of 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 Company intends to further analyze the data from EPITOPE and explore regulatory pathways for Viaskin Peanut in children ages 1 to 3 years, given the high unmet need and absence of approved treatments for this vulnerable population.

***Viaskin Peanut for Children ages 4-7***

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)/Ethics Committee (EC) approval.

---

**Table of Contents**

On September 21, 2022, we announced we had received feedback from the FDA in the form of a partial clinical hold on VITESSE. In the partial clinical hold letter, the FDA specified changes to elements of the VITESSE protocol, acknowledging the intent for the trial to support a future BLA submission. In the following months, we engaged with the FDA to address the feedback provided in the partial clinical hold letter and to finalize the VITESSE protocol. In addition, we continued internal preparations for VITESSE and conducted certain site assessment and start-up activities for prompt study launch once the partial clinical hold was lifted.

On December 23, 2022, we announced the FDA lifted the partial clinical hold and confirmed we satisfactorily addressed all clinical hold issues. The FDA stated that VITESSE may proceed with the revised trial protocol.

**Financing**

In May 2022, the Company announced that pursuant to the Company's At-The-Market program established in May 2022 (the "ATM Program"), it had issued and completed sales of new ordinary shares (the "Ordinary Shares") in form of American Depository Shares ("ADSs"), for a total gross amount of \$ 15.3 million (\$ 14.1 million net of transaction costs). In this context, 6,036,238 new Ordinary Shares in form of ADS have been issued through a capital increase without preferential subscription rights of the shareholders reserved to specific categories of persons fulfilling certain characteristics (the "ATM Issuance"), at a unit subscription price of 1.27 dollar per ADS (i.e., a subscription price per Ordinary Share of 2.41 euro based on the USD/EUR exchange rate of 1.0531 dollar for 1 euro, as published by the European Central Bank on May 4, 2022) and each ADS giving the right to receive one-half of one ordinary share of the Company.

In June 2022, the Company announced an aggregate \$ 194 million (\$ 180.4 million net of transaction costs) private investment in public equity ("PIPE") financing (corresponding to € 181 million on the basis of an exchange rate of \$ 1.0739 = €1.00 published by the European Central Bank on June 8, 2022) 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 were sold to the purchasers 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. Gross proceeds from the PIPE financing total approximately \$ 194 million (corresponding to € 181 million), before deducting private placement expenses.

The ordinary shares, including the ordinary shares issuable upon exercise of the pre-funded warrants from the PIPE financing, have not been registered under the Securities Act of 1933, as amended, and may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements. In connection with the PIPE financing, the Company entered into a registration rights agreement (the "Registration Rights Agreement"), pursuant to which the Company has filed a registration statement with the Securities and Exchange Commission (the "SEC") registering the resale of 59,269,629 ordinary shares issued in the PIPE financing, including ordinary shares underlying the pre-funded warrants.

**COVID-19 Pandemic**

On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. During the COVID-19 pandemic, the Company experienced a decrease in new patients enrolling in the ongoing clinical studies and had to adapt the protocols of its clinical trials because patients were subject to travel restrictions and other containment measures.

The Company has continued to assess the impact of the COVID-19 pandemic and uncertainties created by the pandemic on our business and the conduct of our clinical. As of December 31, 2022, those uncertainties were taken into account in the assumptions underlying the estimates and judgments used by the Company. The Company continues to update these estimates and assumptions as the situation evolves. The effects of the

---

[Table of Contents](#)

COVID-19 pandemic are presented in the relevant line items of the Consolidated Statement of Financial Position and the Consolidated Statement of Operations and Comprehensive Loss according to the function or nature of the income or expense.

**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.

**Class Action Complaint Dismissal**

A class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint, as amended, alleged that the Company and its former Chief Executive Officer, its current Chief Executive Officer, its former Deputy Chief Executive Officer, and its 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 seek unspecified damages on behalf of a purported class of persons that purchased the Company's securities between February 14, 2018 and August 4, 2020 and also held the Company's securities on December 20, 2018 and/or March 16, 2020 and/or August 4, 2020.

A hearing was held on July 29, 2021 in the U.S. District Court for the District of New Jersey where the Court entered an order granting the Company's Motion to Dismiss the Second Amended Class Action Complaint without prejudice. As the dismissal was without prejudice, the Plaintiffs replead their case by filing a Third Amended Class Action Complaint on September 30, 2021 in the same Court. The company moved to dismiss third amended complaint on December 10, 2021.

On July 29, 2022, the Court entered an order granting the Company's Motion to Dismiss the Plaintiff's Third Amended Complaint with prejudice. The Court indicated that the Third Amended Complaint was deficient in a number of ways, failing to allege a violation of the Securities Exchange Act of 1934, and ordered the matter closed. Per court procedural rules, the Plaintiffs had 30 days to appeal the dismissal of the Third Amended Complaint. This Plaintiffs failed to file an appeal of the dismissal of the Third Amended Complaint within the 30-day period and this matter is resolved with finality.

**Note 3 Cash and Cash Equivalents**

The following table presents for each reported period, the breakdown of cash and cash equivalents:

|   | <b>December 31,</b> |               |
|---|---------------------|---------------|
|   | <b>2022</b>         | <b>2021</b>   |
| Cash  | 30,104              | 31,427        |
| Cash equivalents  | 179,090             | 45,874        |
| <b>Total cash and cash equivalents as reported in statement of financial position</b> | <b>209,194</b>      | <b>77,301</b> |
| Bank overdrafts   | —                   | —             |
| <b>Total net cash and cash equivalents as reported in the statement of cash flow</b>  | <b>209,194</b>      | <b>77,301</b> |

---

[Table of Contents](#)

Cash equivalents are immediately convertible into cash at no or insignificant cost on demand. They are measured using level 1 fair value measurements.

**Note 4 Other Current Assets**

Other current assets consisted of the following:

|                     | <u>December 31,</u> |               |
|---------------------|---------------------|---------------|
|                     | <u>2022</u>         | <u>2021</u>   |
| Research tax credit | 5,792               | 28,092        |
| Other tax claims    | 3,903               | 3,561         |
| Prepaid expenses    | 2,680               | 4,149         |
| Other receivables   | 1,504               | 1,282         |
| <b>Total</b>        | <b>13,880</b>       | <b>37,085</b> |

The other tax claims are primarily related to deductible VAT. Prepaid expenses are comprised primarily of insurance expenses, as well as legal and scientific consulting fees. 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 and Medium-sized Enterprises, or SMEs, status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit.

During the year ended December 31, 2022, the Company received the reimbursement of \$ 26.1 million of the 2019, 2020 and 2021 fiscal year research tax credit.

The variance in Research Tax Credit during the two years disclosed is presented as follow:

|   | <u>Amount in</u> | <u>US Dollars</u> |
|---|------------------|-------------------|
| <b>Opening balance sheet receivable as of January 1, 2021</b>   | <b>22,650</b>    |                   |
| + 2021 fiscal year research tax credit                          | 7,505            |                   |
| - Payment received  | (2,063)          |                   |
| <b>Closing balance sheet receivable as of December 31, 2021</b> | <b>28,092</b>    |                   |
| Of which—Non-current portion                                    | —                |                   |
| Of which—Current portion  | 28,092           |                   |

|   | Amount in<br>thousands of<br>US Dollars |
|---|---|
| <b>Opening balance sheet receivable as of January 1, 2022</b>   | 28,092                                  |
| + 2022 fiscal year research tax credit                          | 5,718                                   |
| - Payment received  | ( 26,117)                               |
| - Adjustment and currency translation effect                    | ( 1,901)                                |
| <b>Closing balance sheet receivable as of December 31, 2022</b> | <b>5,792</b>                            |
| <i>Of which—Non-current portion</i>                             | —                                       |
| <i>Of which—Current portion</i>                                 | 5,792                                   |

**Note 5 Property, Plant, and Equipment**

Property and equipment, net consisted of the following:

|  | 1/1/2021      | Currency<br>translation<br>effect | Increase        | Decrease        | 12/31/2021    |
|--|---------------|-----------------------------------|-----------------|-----------------|---------------|
| Laboratory equipment                           | 23,072        | ( 1,783)                          | 853             | ( 708)          | 21,434        |
| Building fixtures                              | 7,767         | ( 408)                            | 48              | ( 3,449)        | 3,958         |
| Office equipment                               | 970           | ( 39)                             | —               | ( 67)           | 864           |
| Computer equipment                             | 1,846         | ( 92)                             | 9               | ( 464)          | 1,299         |
| Property, plant, and equipment in progress     | 7,828         | ( 477)                            | —               | ( 2,960)        | 4,390         |
| <b>Total, gross</b>                            | <b>41,482</b> | <b>( 2,799)</b>                   | <b>910</b>      | <b>( 7,648)</b> | <b>31,945</b> |
| Less accumulated amortization and depreciation | ( 16,690)     | 1,109                             | ( 4,437)        | 6,219           | ( 13,799)     |
| <b>Total, net</b>                              | <b>24,792</b> | <b>( 1,690)</b>                   | <b>( 3,527)</b> | <b>( 1,429)</b> | <b>18,146</b> |

|  | 1/1/2022      | Currency<br>translation<br>effect | Increase        | Decrease        | Relocation | 12/31/2022    |
|--|---------------|-----------------------------------|-----------------|-----------------|------------|---------------|
| Laboratory equipment                           | 21,434        | ( 1,246)                          | —               | —               | 270        | 20,459        |
| Building fixtures                              | 3,958         | ( 196)                            | 55              | ( 604)          | —          | 3,214         |
| Office equipment                               | 864           | ( 25)                             | 74              | ( 428)          | —          | 485           |
| Computer equipment                             | 1,299         | ( 65)                             | 16              | —               | 8          | 1,258         |
| Property, plant, and equipment in progress     | 4,390         | ( 252)                            | 608             | —               | ( 278)     | 4,468         |
| <b>Total, gross</b>                            | <b>31,945</b> | <b>( 1,783)</b>                   | <b>754</b>      | <b>( 1,032)</b> | <b>—</b>   | <b>29,884</b> |
| Less accumulated amortization and depreciation | ( 13,799)     | 703                               | ( 2,723)        | 1,031           | —          | ( 14,788)     |
| <b>Total, net</b>                              | <b>18,146</b> | <b>( 1,080)</b>                   | <b>( 1,968)</b> | <b>( 1)</b>     | <b>—</b>   | <b>15,096</b> |

The depreciation and amortization expense for each of the years ended December 31, 2022 and 2021 was \$ 2.7 million and \$ 4.4 million respectively.

Laboratory equipment increase in 2021 was mainly driven by commissioning of industrial equipment.

**Note 6 Lease contracts**

Future minimum lease payments under the Company's operating leases' right of use as of December 31, 2022 and 2021, are as follows:

|   | December 31, 2022 |                 |              | December 31, 2021 |                 |               |
|---|-------------------|-----------------|--------------|-------------------|-----------------|---------------|
|   | Real<br>estate    | Other<br>assets | Total        | Real<br>estate    | Other<br>assets | Total         |
| Current portion                               |                   |                 |              |                   |                 |               |
| Year 2  | 1,972             | 79              | 2,051        | 3,361             | 77              | 3,438         |
| Year 3  | 1,168             | 74              | 1,243        | 3,124             | 23              | 3,147         |
| Year 4  | 65                | 6               | 71           | 2,299             | 18              | 2,317         |
| Year 5  | —                 | —               | —            | 771               | 1               | 773           |
| Thereafter                                    | —                 | —               | —            | 790               | —               | 790           |
| <b>Total minimum lease payments</b>           | <b>3,204</b>      | <b>160</b>      | <b>3,364</b> | <b>11,565</b>     | <b>119</b>      | <b>11,684</b> |
| Less: Effects of discounting                  | (325)             | (17)            | (343)        | (1,526)           | (8)             | (1,534)       |
| <b>Present value of operating lease</b>       | <b>2,879</b>      | <b>143</b>      | <b>3,021</b> | <b>10,039</b>     | <b>111</b>      | <b>10,150</b> |
| Less: current portion                         | (1,823)           | (71)            | (1,894)      | (2,929)           | (74)            | (3,003)       |
| <b>Long-term operating lease</b>              | <b>1,055</b>      | <b>72</b>       | <b>1,127</b> | <b>7,110</b>      | <b>37</b>       | <b>7,147</b>  |
| Weighted average remaining lease term (years) | 1.40              | —               | —            | 4.14              | 2.01            | —             |
| Weighted average discount rate                | 3.00%             | 2.45%           | —            | 4.84%             | 3.32%           | —             |

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:

|                         | December 31, |       |
|-------------------------|--------------|-------|
|                         | 2022         | 2021  |
| Operating lease expense | 1,800        | 3,027 |
| Net termination impact  | (1,657)      | —     |

In January 2022, the company entered into a termination agreement for its U.S. office in Summit, NJ, following the resizing of its facility use. The Company recognized an income of \$ 1.2 million as of June 30, 2022 due to the early termination of its Summit, NJ lease, offset by the payment of a one-time lump sum early termination fee of \$ 1.5 million.

On March 28, 2022, the Company entered into a binding office lease agreement in New Jersey for a lease term of 3 years and 2 months . The lease commencement was based upon delivery of possession of the premises by the Landlord and occurred on April 1, 2022. Right of use and related lease debt have been recorded starting April 1, 2022 for a gross amount of \$ 0.4 million.

Supplemental cash flow information related to operating leases is as follows for the period December 31, 2022 and 2021:

|  | December 31, |       |
|--|--------------|-------|
|  | 2022         | 2021  |
| Cash paid for amounts included in the measurement of lease liabilities | —            | —     |
| Operating cash flows from operating leases                             | 2,195        | 2,879 |

**Note 7 Other non-current assets**

Other non-current assets consisted of the following:

|   | <u>December 31,</u> |              |
|---|---------------------|--------------|
|   | <u>2022</u>         | <u>2021</u>  |
| FX facility collateral account                                      | 3,739               | 3,969        |
| Deposits, pledged securities and other non-current financial assets | 1,773               | 2,665        |
| Liquidity contract  | 312                 | 199          |
| <b>Total other non-current assets</b>                               | <b>5,824</b>        | <b>6,833</b> |

The other non-current assets are composed of security deposits paid to premises lessors, pledged securities, the liquidity contract and a collateral account to guarantee a FX facility not used as of December 31, 2022.

Under the liquidity contract, 149,793 treasury shares were allocated as a reduction of Shareholders' Equity as at December 31, 2022 with 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:

|                 | <u>December 31,</u> |               |
|-----------------|---------------------|---------------|
|                 | <u>2022</u>         | <u>2021</u>   |
| Social debt     | 5,872               | 6,708         |
| Deferred income | 2,137               | 4,146         |
| Tax liabilities | 69                  | 182           |
| Other debts     | 1,131               | 1,325         |
| <b>Total</b>    | <b>9,210</b>        | <b>12,361</b> |

The other current liabilities include short-term debt related to employees' bonus accruals, as well as social welfare and tax agencies.

Deferred income mainly includes deferred income from the collaboration agreement with Nestlé Health Science, which amounted to \$ 2.1 million as of December 31, 2022.

**Note 9 Financial debt and Other Non-Current Liabilities**

**Financial debt—Conditional Advances**

The table below presents the details of the debts recorded on the statement of financial position by the type of conditional advance:

|   | BPI<br>advance |
|---|----------------|
| <b>Balance sheet debt at start of period 01/01/2021</b> | <b>1,267</b>   |
| Repayments  | ( 689)         |
| Other movements   | ( 68)          |
| <b>Balance sheet debt as at 12/31/2021</b>              | <b>510</b>     |
| Of which—Non-current portion                            | —              |
| Of which—Current portion                                | 510            |
| Stated interest rate                                    | No             |
| Discount rate   | 3.2%           |
| Maturity (in years)                                     | 2 - 7          |
| <br>  |                |
|   | BPI<br>advance |
| <b>Balance sheet debt at start of period 01/01/2022</b> | <b>510</b>     |
| Repayments  | ( 474)         |
| Other movements   | ( 36)          |
| <b>Balance sheet debt as at 12/31/2022</b>              | <b>—</b>       |
| Stated interest rate                                    | No             |
| Discount rate   | 3.2%           |
| Maturity (in years)                                     | 2 - 7          |

The changes appearing in "Other movements" are comprised of the effect of discounting conditional advances.

**BpiFrance Financement Interest Free Loan**

The Company has been granted until September 2022 a € 3.0 million interest-free Innovation loan from BpiFrance Financement to help financing the pharmaceutical development of Viaskin™ Milk. This amount was received in a single disbursement on November 27, 2014.

**Due dates of liabilities**

The following table shows the maturity of the Company's liabilities (except leases disclosed in Note 7—"Lease contract"):

|  | Carrying      | 2023          | 2024         | Thereafter |
|--|---------------|---------------|--------------|------------|
| Other liabilities                              | 13,945        | 9,210         | 4,735        | —          |
| Supplier accounts payable and related payables | 14,473        | 14,473        | —            | —          |
| <b>Total liabilities</b>                       | <b>28,418</b> | <b>23,683</b> | <b>4,735</b> | <b>—</b>   |

As detailed in Note 8, the current portion of other liabilities mainly includes social security and deferred incomes from the collaboration agreement with Nestlé Health Science.

**Note 10 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.

---

## Table of Contents

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, accounts receivable, deposits, liquidity contract, accounts payable and conditional advances. The fair values of these financial instruments are deemed to approximate their carrying amount.

The fair values of cash and cash equivalents, accounts receivable, deposits, liquidity contract and accounts payable are categorized as Level 1. The fair value of conditional advance was categorized as Level 2 and was estimated based on a discounted cash flow method using the effective interest rate. For the interest-free conditional advances, the discount rate applied is equal to the rate of fungible treasury bonds over the time period that corresponds to the time period of the repayment of the advances.

There has been no transfer between levels of the fair value hierarchy during the years ended December 31, 2021 and 2022.

### Note 11 Share Capital Issued

The share capital, as of December 31, 2022, is set at the sum of € 9,413,715 (\$ 10,720,399 converted at historical rates). It is divided into 94,137,145 fully authorized, subscribed and paid-up shares with a nominal value of € 0.10 .

This number does not reflect ordinary shares issuable upon exercise or settlement of non-employee warrants ("BSA"), stock options ("SO") and restricted stock units ("RSU") granted to both employees and non-employees of the Company.

All the shares give their owners the right to a proportional share of the income and the net assets of the Company.

Pursuant to the authorization granted by the SH General Meeting, the Board of Directors, at its meeting of June 9, 2022 (the "Board General Meeting"):

- decided, within the framework of the PIPE financing the principle of a capital increase in cash with cancellation of preferential subscription rights, reserved for categories of persons meeting the characteristics set out in the 18<sup>th</sup> resolution of the Board General Meeting, through the issuance of Ordinary Shares and warrants to subscribe for Ordinary Shares, for a maximum amount of 6,113,200 New Ordinary Shares, corresponding to the maximum issue ceiling under the 22<sup>nd</sup> resolution of the Board General Meeting;
- granted a number of authorizations for the purpose of carrying out the issuance;
- sub-delegated its authority to the Chief Executive Officer for the purpose of implementing the financing.

The Chief Executive Officer, acting pursuant to the sub-delegations of authority granted by the Board of Directors of the Company on June 8, 2022, after receiving the favorable opinion of the Pricing Committee established by the Board of Directors, has, on June 9, 2022:

- decided, making use of the 18<sup>th</sup> resolution of the Board General Meeting, to proceed with a capital increase in cash with cancellation of preferential subscription rights reserved for categories of investors, in accordance with the Article L. 225-128 of French Commercial Code, an amount of € 3,285,566.90 , through the issuance of (i) 32,855,669 New Ordinary Shares, to be subscribed in cash at a unit price of € 2.90 of share premium) and to be fully paid up at the time of subscription, i.e. a

---

[Table of Contents](#)

capital increase of a nominal amount of € 3,285,566.90 together with a share premium of € 95,281,440.10 , i.e. a gross amount of the capital increase of € 98,567,007 , and (ii) 28,276,331 prefunded warrants to be subscribed in cash by paying up on the date of issue of € 82,001,359.90 corresponding to the prepayment of the subscription price of the new ordinary shares in the event of exercise of the prefunded warrants,

- decided to set the maximum nominal amount of the capital increase resulting from the full exercise of the prefunded warrants at € 2,827,633.10 , by issuing a maximum of 28,276,331 ordinary shares, with a value of € 0.10 to be subscribed in cash at the price of € 0.10 euro (without share premium), and to be fully paid up at the time of subscription, i.e. a capital increase of a maximum nominal amount of € 2,827,633.10 (and a share premium corresponding to the amount of the pre-financed price released in advance at the time of the subscription of the prefunded warrants ), being specified that this amount does not take into account the nominal value of the ordinary shares to be issued in order to preserve the rights of the holders of securities giving access to the capital issued or to be issued, in accordance with the legal and regulatory provisions and the contractual stipulations providing for other cases of adjustment if necessary;
- determined the list of beneficiaries (designated within each of the categories of persons defined in the 18<sup>th</sup> resolution of the Board General Meeting) and the number of New Ordinary Shares and warrants allocated to each of them under the conditions defined in the 18th resolution of the Board General Meeting beneficiaries under the conditions defined in section 5 of the offering circular relating to the PIPE financing.

The Company has assessed the pre-funded warrants for appropriate equity or liability classification. During this assessment, the Company determined the pre-funded warrants are freestanding instruments that do not meet the definition of a liability pursuant to ASC 480 and do not meet the definition of a derivative pursuant to ASC 815.

The 2022 Warrants are classified as a component of permanent equity because they are 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 do not provide any guarantee of value or return.

Accordingly, the pre-funded warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance.

The changes in number of outstanding prefunded warrants are as follows:

|  | Prefunded<br>warrants    |
|--|--------------------------|
| <b>Balance as of December 31, 2021</b> | <u>—</u>                 |
| Granted during the period              | 28,276,331               |
| Forfeited during the period            | —                        |
| Exercised/released during the period   | —                        |
| Expired during the period              | —                        |
| <b>Balance as of December 31, 2022</b> | <b><u>28,276,331</u></b> |

[Table of Contents](#)

The table below presents the changes in the share capital of the Company as of December 31, 2021 and 2022:

(Amounts in thousands of U.S. Dollars except share and per share data)

| Date                                   | Nature of the transactions                 | Share capital* | Additional paid-in capital | Number of shares  |
|--|--|----------------|----------------------------|-------------------|
| <b>Balance as of December 31, 2020</b> |  | <b>6,518</b>   | <b>1,152,042</b>           | <b>54,929,187</b> |
| 02/22/2021                             | Capital increase by employee warrants      | 1              | 46                         | 7,500             |
| 05/12/2021                             | Capital increase by employee warrants      | 1              | 62                         | 10,200            |
| 05/17/2021                             | Capital increase by employee warrants      | 1              | 64                         | 10,500            |
| 05/18/2021                             | Capital increase by employee warrants      | 1              | 66                         | 10,800            |
| 05/19/2021                             | Retained earnings charged on share premium |                | ( 797,823)                 |                   |
| 05/21/2021                             | Capital increase by employee warrants      | 1              | 68                         | 11,100            |
| 05/26/2021                             | Capital increase by employee warrants      | 3              | 129                        | 21,000            |
| 05/28/2021                             | Capital increase by employee warrants      | 1              | 70                         | 11,400            |
| 06/10/2021                             | Issuance of share warrants                 |                | 279                        |                   |
| 10/07/2021                             | Capital increase by ordinary shares        | 2              | ( 2)                       | 20,000            |
| 11/24/2021                             | Capital increase by ordinary shares        | 7              | ( 7)                       | 58,675            |
| 12/20/2021                             | Capital increase by ordinary shares        | 1              | ( 1)                       | 5,400             |
| 12/31/2021                             | Share-based payments                       |                | 3,122                      |                   |
| <b>Balance as of December 31, 2021</b> |  | <b>6,538</b>   | <b>358,115</b>             | <b>55,095,762</b> |
| 03/23/2022                             | Capital increase by ordinary shares        | 0              | ( 0)                       | 775               |
| 05/10/2022                             | Capital increase by ATM program            | 637            | 13,442                     | 6,036,238         |
| 05/12/2022                             | Retained earnings charged on share premium |                | ( 95,209)                  |                   |
| 05/19/2022                             | Capital increase by employee warrants      | 1              | ( 1)                       | 5,000             |
| 05/24/2022                             | Capital increase by employee warrants      | 3              | ( 3)                       | 26,135            |
| 06/09/2022                             | Capital increase by ordinary shares        | 3,530          | 88,743                     | 32,855,669        |
| 06/09/2022                             | Capital increase by share warrants         |                | 88,094                     |                   |
| 06/10/2022                             | Capital increase by employee warrants      | 0              | 13                         | 3,100             |
| 07/08/2022                             | Capital increase by employee warrants      | 0              | 10                         | 2,513             |
| 09/23/2022                             | Capital increase by ordinary shares        | 0              | ( 0)                       | 249               |
| 11/19/2022                             | Capital increase by ordinary shares        | 0              | ( 0)                       | 2,500             |
| 11/22/2022                             | Capital increase by ordinary shares        | 3              | ( 3)                       | 30,625            |
| 11/24/2022                             | Capital increase by ordinary shares        | 8              | ( 8)                       | 78,579            |
| 12/31/2021                             | Share-based payments                       |                | 5,026                      |                   |
| <b>Balance as of December 31, 2022</b> |  | <b>10,720</b>  | <b>458,220</b>             | <b>94,137,145</b> |

\* Conversion in U.S. Dollars at historical rates

In May 2022, pursuant to the authorization granted by the General Meeting of the Shareholders held on May 12, 2022, the accumulated net losses of DBV Technologies S.A. after appropriation of the net result for the year ended December 31, 2021 have been allocated to additional paid-in capital in the amount of € 81.2 million (\$ 95.2 million converted at historical rates).

**Note 12 Share-Based Payments**

The Board of Directors has been authorized by the General Meeting of the Shareholders to grant restricted stock units ("RSU"), stock options plan ("SO"), and non-employee warrants (Bons de Souscription d'Actions or "BSA"), as follows:

| Share-based payments instrument | General meeting of shareholders | Board of directors meeting | Grant date | Number granted |
|---------------------------------|---------------------------------|----------------------------|------------|----------------|
| BSA                             | 12/9/11                         | 9/25/12                    | 9/25/12    | 30,000         |
| BSA                             | 6/4/13                          | 7/25/13                    | 7/25/13    | 73,000         |
| SO                              | 12/9/11                         | 9/18/13                    | 9/18/13    | 518,000        |
| BSA                             | 6/3/14                          | 3/24/15                    | 3/24/15    | 10,000         |
| SO                              | 6/3/14                          | 6/23/15                    | 6/23/15    | 120,000        |
| BSA                             | 6/2/15                          | 11/19/15                   | 11/19/15   | 22,500         |
| BSA                             | 6/2/15                          | 12/15/15                   | 2/15/16    | 90,000         |
| SO                              | 6/3/14                          | 4/6/16                     | 4/21/16    | 33,000         |
| SO                              | 6/3/14                          | 6/21/16                    | 6/21/16    | 110,000        |
| BSA                             | 6/2/16                          | 6/21/16                    | 8/21/16    | 20,000         |
| SO                              | 6/3/14                          | 6/21/16                    | 9/15/16    | 9,300          |
| SO                              | 6/3/14                          | 6/21/16                    | 10/17/16   | 16,500         |
| BSA                             | 6/2/16                          | 12/9/16                    | 2/9/16     | 59,000         |
| SO                              | 6/3/14                          | 6/21/16                    | 12/9/16    | 74,960         |
| RSU                             | 9/2/15                          | 3/14/17                    | 3/14/17    | 22,500         |
| RSU                             | 9/2/15                          | 4/20/17                    | 4/20/17    | 24,000         |
| BSA                             | 6/15/17                         | 6/15/17                    | 8/15/17    | 9,000          |
| SO                              | 6/3/14                          | 6/15/17                    | 6/15/17    | 126,000        |
| SO                              | 6/15/17                         | 6/15/17                    | 6/15/17    | 111,600        |
| SO                              | 6/15/17                         | 6/15/17                    | 9/15/17    | 52,600         |
| SO                              | 6/15/17                         | 11/17/17                   | 12/5/17    | 625,200        |
| BSA                             | 6/15/17                         | 5/2/18                     | 7/2/18     | 44,000         |
| RSU                             | 6/2/18                          | 6/22/18                    | 6/22/18    | 486,153        |
| RSU                             | 6/2/18                          | 9/6/18                     | 9/6/18     | 450            |
| SO                              | 6/2/18                          | 9/6/18                     | 9/6/18     | 65,000         |
| SO                              | 6/2/18                          | 6/22/18                    | 10/15/18   | 76,700         |
| RSU                             | 6/2/18                          | 11/1/18                    | 11/1/18    | 57,000         |
| SO                              | 6/2/18                          | 11/29/18                   | 11/29/18   | 350,000        |
| RSU                             | 6/2/18                          | 12/1/18                    | 12/12/18   | 16,250         |
| RSU                             | 6/2/18                          | 12/1/18                    | 12/17/18   | 3,000          |
| SO                              | 6/2/18                          | 3/4/19                     | 3/20/19    | 547,100        |
| RSU                             | 6/2/18                          | 5/10/19                    | 5/10/19    | 100,000        |
| SO                              | 5/24/19                         | 5/24/19                    | 5/24/19    | 150,000        |
| SO                              | 5/24/19                         | 7/1/19                     | 7/1/19     | 403,400        |
| SO                              | 5/24/19                         | 7/1/19                     | 7/22/19    | 75,000         |
| RSU                             | 5/24/19                         | 10/1/19                    | 10/11/19   | 40,000         |
| SO                              | 5/24/19                         | 10/1/19                    | 1/15/20    | 94,500         |
| RSU                             | 5/24/19                         | 10/11/19                   | 3/16/20    | 5,000          |
| RSU                             | 4/20/20                         | 4/20/20                    | 4/29/20    | 20,000         |
| RSU                             | 4/20/20                         | 11/24/20                   | 11/24/20   | 475,000        |
| SO                              | 4/20/20                         | 11/24/20                   | 11/24/20   | 1,216,200      |
| RSU                             | 4/20/20                         | 3/23/21                    | 3/23/21    | 24,900         |
| SO                              | 4/20/20                         | 3/23/21                    | 3/23/21    | 75,200         |
| RSU                             | 5/19/21                         | 5/19/21                    | 5/19/21    | 20,000         |

---

**Table of Contents**

|     |         |          |          |           |
|-----|---------|----------|----------|-----------|
| BSA | 5/19/21 | 5/19/21  | 6/3/21   | 39,185    |
| RSU | 5/19/21 | 11/22/21 | 11/22/21 | 257,300   |
| SO  | 5/19/21 | 11/22/21 | 11/22/21 | 1,107,300 |
| RSU | 5/19/21 | 5/12/22  | 5/12/22  | 3,200     |
| SO  | 5/19/21 | 5/12/22  | 5/12/22  | 19,000    |
| RSU | 5/12/22 | 7/29/22  | 7/29/22  | 66,700    |
| SO  | 5/12/22 | 7/29/22  | 7/29/22  | 135,500   |
| RSU | 5/12/22 | 11/21/22 | 11/21/22 | 519,650   |
| SO  | 5/12/22 | 11/21/22 | 11/21/22 | 1,771,786 |

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.

**12.1 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 € 5.13 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 during the year ended December 31, 2021 |          |
|--|----------|
| 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 €)                         | —        |

The following table summarizes all BSA activity during the year ended December 31, 2021:

|  | Number of warrants outstanding | Weighted-average exercise price (in Euros) | Weighted-average remaining contractual term (in years) | Aggregate intrinsic value (in thousands of Euros) |
|--|--------------------------------|--|--|---|
| <b>Balance as of December 31, 2020</b>       | <b>218,008</b>                 | <b>52.78</b>                               | <b>5.36</b>  | —   |
| Granted during the period                    | 39,185                         | 9.18                                       | —  | —   |
| Forfeited during the period                  | —                              | —  | —  | —   |
| Exercised during the period                  | —                              | —  | —  | —   |
| Expired during the period                    | (500)                          | 5.13                                       | —  | —   |
| <b>Balance as of December 31, 2021</b>       | <b>256,693</b>                 | <b>47.51</b>                               | <b>4.35</b>  | —   |
| Warrants exercisable as of December 31, 2021 | 256,693                        | 47.51                                      | 4.35   | —   |

The following table summarizes all BSA warrants activity during the year ended December 31, 2022:

|  | Number of warrants outstanding | Weighted-average exercise price (in Euros) | Weighted-average remaining contractual term (in years) | Aggregate intrinsic value (in thousands of Euros) |
|--|--------------------------------|--|--|---|
| <b>Balance as of December 31, 2021</b>       | <b>256,693</b>                 | <b>47.51</b>                               | <b>4.35</b>  | —   |
| Granted during the period                    | —                              | —  | —  | —   |
| Forfeited during the period                  | —                              | —  | —  | —   |
| Exercised during the period                  | —                              | —  | —  | —   |
| Expired during the period                    | (5,000)                        | 8.59                                       | —  | —   |
| <b>Balance as of December 31, 2022</b>       | <b>251,693</b>                 | <b>48.29</b>                               | <b>4.36</b>  | —   |
| Warrants exercisable as of December 31, 2022 | 251,693                        | 48.29                                      | 4.36   | —   |

#### 12.2 Employee warrants

As of December 31, 2022, no more BSPCE / BCE warrants (Bons de Souscription de Parts de Créeateur d'Entreprise or "BSPCE") are exercisable.

#### 12.3 Stock options

The Company's Board of Directors has been authorized by the shareholders' general meeting to grant SOs 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 € 2.61 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 after January 15, 2020, SO granted mainly vest over four years at a rate of 25 % upon the first anniversary of the issuance date and 12.5 % every 6 months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions).

[Table of Contents](#)

- 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 6 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,

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, 2021:

|  | <b>Number of SO outstanding</b> | <b>Weighted-average exercise price in Euros</b> | <b>Weighted-average remaining contractual term (in years)</b> | <b>Aggregate intrinsic value in thousands of Euros</b> |
|--|---------------------------------|---|---|--|
| <b>Balance as of December 31, 2020</b>             | <b>2,610,510</b>                | <b>18.75</b>                                    | <b>8.17</b>   | <b>198.8</b>   |
| Granted during the period                          | 1,182,900                       | 6.09  | —   | —  |
| Forfeited during the period                        | (162,200)                       | 4.89  | —   | —  |
| Exercised during the period                        | —                               | —   | —   | —  |
| Expired during the period                          | —                               | —   | —   | —  |
| <b>Balance as of December 31, 2021</b>             | <b>3,631,210</b>                | <b>15.25</b>                                    | <b>8.67</b>   | <b>—</b>   |
| <b>Options exercisable as of December 31, 2021</b> | <b>878,560</b>                  | <b>29.50</b>                                    | <b>6.13</b>   | <b>—</b>   |

The following table summarizes all stock options activity during the year ended December 31, 2022:

|  | <b>Number of SO outstanding</b> | <b>Weighted-average exercise price in Euros</b> | <b>Weighted-average remaining contractual term (in years)</b> | <b>Aggregate intrinsic value in thousands of Euros</b> |
|--|---------------------------------|---|---|--|
| <b>Balance as of December 31, 2021</b>             | <b>3,631,210</b>                | <b>15.25</b>                                    | <b>8.67</b>   | <b>—</b>   |
| Granted during the period                          | 1,926,286                       | 3.12  | —   | —  |
| Forfeited during the period                        | (238,715)                       | 12.22   | —   | —  |
| Exercised during the period                        | 5,613                           | 4.16  | —   | —  |
| Expired during the period                          | —                               | —   | —   | —  |
| <b>Balance as of December 31, 2022</b>             | <b>5,313,169</b>                | <b>11.00</b>                                    | <b>8.41</b>   | <b>—</b>   |
| <b>Options exercisable as of December 31, 2022</b> | <b>1,331,508</b>                | <b>20.20</b>                                    | <b>6.69</b>   | <b>—</b>   |

As of December 31, 2022, there was € 9.3 million (\$ 9.9 million converted at closing rate) of unrecognized SO expense that is expected to be recognized over a weighted-average period of 3.4 years.

**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:

|   | Assumptions per year ended, December 31, |        |       |        |        |         |       |
|---|--|--------|-------|--------|--------|---------|-------|
|   | Prior to<br>2017                         | 2017   | 2018  | 2019   | 2020   | 2021    | 2022  |
| Stock options per grant date                        |  |        |       |        |        |         |       |
| Weighted average shares price at grant date in €    | 36.69                                    | 45.49  | 31.86 | 15.26  | 5.54   | 5.71    | 2.33  |
| Weighted average expected volatility                | 45.4%                                    | 41.0%  | 47.1% | 70.8%  | 87.3%  | 90.2%   | 98.9% |
| Weighted average risk-free interest rate            | 1.0%                                     | (0.1)% | 0.3%  | (0.1)% | (0.5)% | (0.06)% | 2.2%  |
| Weighted average expected term (in years)           | 6.7                                      | 6      | 6     | 6      | 6      | 6       | 6     |
| Dividend yield                                      | 0  | 0      | 0     | 0      | 0      | 0       | 0     |
| Weighted average fair value of stock-options (in €) | 17.66                                    | 17.16  | 13.67 | 9.65   | 3.90   | 4.17    | 2.23  |

**12.4 Restricted stock units**

The Company's board of directors has been authorized by the shareholders' general meeting to grant RSUs to employees.

[Table of Contents](#)

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);
- Since November 24, 2020, RSUs vest over four years at a rate of 25% upon the first anniversary of the issuance date and 12.5% every 6 months thereafter, subject to the beneficiary being still employed by the Company (except in specific 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, 2021:

|  | Number of<br>RSU<br>outstanding | Weighted<br>average grant<br>date fair<br>value in<br>Euros |
|--|---------------------------------|---|
| <b>Balance as of December 31, 2020</b> | <b>1,118,745</b>                | <b>20.35</b>  |
| Granted during the period              | 302,200                         | 6.13  |
| Forfeited during the period            | (96,350)                        | 6.74  |
| Released during the period             | (84,075)                        | 8.20  |
| Expired during the period              | —                               | —   |
| <b>Balance as of December 31, 2021</b> | <b>1,240,520</b>                | <b>18.77</b>  |

The following table summarizes all RSUs activity for the year ended December 31, 2022:

|  | Number of<br>RSU<br>outstanding | Weighted<br>average grant<br>date fair<br>value in<br>Euros |
|--|---------------------------------|---|
| <b>Balance as of December 31, 2021</b> | <b>1,240,520</b>                | <b>18.77</b>  |
| Granted during the period              | 589,550                         | 2.67  |
| Forfeited during the period            | (92,326)                        | 4.96  |
| Released during the period             | (118,967)                       | 5.15  |
| Expired during the period              | —                               | —   |
| <b>Balance as of December 31, 2022</b> | <b>1,618,778</b>                | <b>14.69</b>  |

[Table of Contents](#)

As of December 31, 2022, there was € 2.6 million (\$ 2.8 million converted at closing rate) of unrecognized RSUs compensation expense that is expected to be recognized over a weighted-average period of 3.4 years.

**12.5 Reconciliation of the share-based payment expenses with the Consolidated Statements of Operations and Comprehensive Loss**

|  | December 31,    |              |
|--|-----------------|--------------|
|  | 2022            | 2021         |
| Research and development                               | SO<br>( 1,462)  | ( 759)       |
|  | RSU<br>( 841)   | ( 887)       |
| Sales and marketing                                    | SO<br>( 31)     | ( 209)       |
|  | RSU<br>( 4)     | ( 104)       |
| General and administrative                             | SO<br>( 2,374)  | ( 841)       |
|  | RSU<br>( 315)   | ( 322)       |
| <b>Total share-based compensation (expense) income</b> | <b>( 5,026)</b> | <b>3,122</b> |

**Note 13 Contingencies**

Non-current contingencies and current contingencies break down as follows:

|                            | December 31,  |               |
|----------------------------|---------------|---------------|
|                            | 2022          | 2021          |
| Current contingencies      | 3,944         | 4,095         |
| Non-current contingencies  | 16,680        | 6,758         |
| <b>Total contingencies</b> | <b>20,625</b> | <b>10,853</b> |

The table below shows movements in contingencies:

|   | Pension<br>retirement<br>obligations | Collaboration<br>agreement—<br>Loss<br>at completion | Other<br>contingencies | Total         |
|---|--------------------------------------|--|------------------------|---------------|
| <b>At January 1, 2021</b>   | <b>937</b>                           | <b>3,956</b>   | <b>2,649</b>           | <b>7,542</b>  |
| Increases in liabilities  | 181                                  | 6,420  | 47                     | 6,649         |
| Used liabilities  | —                                    | —  | ( 1,634)               | ( 1,634)      |
| Reversals of unused liabilities   | —                                    | —  | ( 920)                 | ( 920)        |
| Net interest related to employee benefits, and<br>unwinding of discount | 3                                    | —  | —                      | 3             |
| Actuarial gains and losses on defined-benefit plans                     | ( 35)                                | —  | —                      | ( 35)         |
| Currency translation effect   | ( 78)                                | ( 577)   | ( 98)                  | ( 753)        |
| <b>At December 31, 2021</b>   | <b>1,008</b>                         | <b>9,800</b>   | <b>45</b>              | <b>10,853</b> |
| <i>Of which Current</i>   | <i>—</i>                             | <i>4,049</i>   | <i>45</i>              | <i>4,095</i>  |
| <i>Of which Non-current</i>   | <i>1,008</i>                         | <i>5,750</i>   | <i>—</i>               | <i>6,758</i>  |

|   | Pension<br>retirement<br>obligations | Collaboration<br>agreement—<br>Loss<br>at completion | Other<br>contingencies | Total         |
|---|--------------------------------------|--|------------------------|---------------|
| <b>At January 1, 2022</b>   | <b>1,008</b>                         | <b>9,800</b>   | <b>45</b>              | <b>10,853</b> |
| Increases in liabilities  | 105                                  | 12,455   | —                      | 12,560        |
| Used liabilities  | —                                    | —  | (42)                   | (42)          |
| Reversals of unused liabilities   | —                                    | (1,984)  | —                      | (1,984)       |
| Net interest related to employee benefits, and unwinding<br>of discount | —                                    | —  | —                      | —             |
| Actuarial gains and losses on defined-benefit plans                     | (262)                                | —  | —                      | (262)         |
| Currency translation effect   | (61)                                 | (436)  | (3)                    | (500)         |
| <b>At December 31, 2022</b>   | <b>790</b>                           | <b>19,835</b>  | <b>—</b>               | <b>20,625</b> |
| <i>Of which Current</i>   | —                                    | 3,944  | —                      | 3,944         |
| <i>Of which Non-current</i>   | 790                                  | 15,891   | —                      | 16,680        |

The Company does not hold any plan assets for any of the periods presented.

As of December 31, 2022, the Company updated its measurement of progress of the Phase 2 clinical trial ("P2") conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. The Company has recorded an accrual in the amount of the excess between the Company's current best estimates of costs yet to be incurred and income yet to be recognized for the completion of the P2.

As part of the estimation of the retirement commitments, the following assumptions were used for all categories of employees:

|                                       | December 31,  |       |
|---------------------------------------|---|-------|
|                                       | 2022  | 2021  |
| % Social security contributions       | 50.0%   | 50.0% |
| Salary increases                      | 2.0%  | 2.0%  |
| Discount rate—iboxx Corporates AA 10+ | 3.77%   | 0.98% |
| Expected staff turnover               | 10.0%   | 10.0% |
| Estimated retirement age              | 65  | 65    |
| Life table                            | TGH05-TGF05   |       |
| Collective agreement                  | National Collective Agreement of<br>the pharmaceutical industry |       |

#### Note 14 Operating Income

The operating income is broken down in the following manner:

|                        | December 31, |              |
|------------------------|--------------|--------------|
|                        | 2022         | 2021         |
| Research tax credit    | 5,718        | 7,505        |
| Other operating income | (874)        | (1,797)      |
| <b>Total</b>           | <b>4,844</b> | <b>5,708</b> |

On May 31, 2016, the Company announced its entry into an exclusive global collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopatch test tool for the diagnosis of cow's milk protein allergy in infants and toddlers. Under the terms of the exclusive collaboration, the Company is responsible for leading the development activities of MAG1C up through a pivotal Phase 3 clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of

[Table of Contents](#)

MAG1C globally, while prioritizing certain agreed-upon countries. The Company entered into an amendment with Nestlé Health Science on July 12, 2018. The Company is eligible to receive up to € 100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of € 10.0 million that the Company received in July 2016.

The Company's current clinical trials, including the Phase 2 clinical trial conducted as part of the development activities pursuant to the Development, Collaboration and License agreement with Nestlé Health Science, have been impacted by the Covid-19 pandemic, among other factors. The Company has experienced difficulties in enrolling new patients in this Phase 2 clinical trial notwithstanding the implementation of a protocol amendment and various other strategies to improve recruitment. As a result of the accumulation of recruitment delays, the Company expects to incur additional clinical and production costs related to the Phase 2 clinical trial as well as delays in achievement of upcoming milestones.

As of December 31, 2022, the Company recorded its collaboration agreement's revenue based on its updated measurement of progress of the Phase 2 clinical trial conducted as part of the agreement. The accrual recorded in the amount of the difference between the Company's current best estimates of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 clinical trial has been updated accordingly.

**Note 15 Allocation of Personnel Expenses**

The Company had 86 average employees for the year ended December 31, 2022, in comparison with 101 employees for the year ended December 31, 2021.

**Allocation of Personnel Expenses by Function:**

|                                     | <b>December 31,</b> |               |
|-------------------------------------|---------------------|---------------|
|                                     | <b>2022</b>         | <b>2021</b>   |
| Research and Development expenses   | 13,055              | 14,596        |
| Sales and Marketing expenses        | 914                 | 1,885         |
| General and Administrative expenses | 10,008              | 9,357         |
| Restructuring*                      | —                   | 5,296         |
| <b>Total personnel expenses</b>     | <b>23,977</b>       | <b>31,135</b> |

\* Restructuring personnel expenses excluding reversal for the year ended December 31, 2021.

**Allocation of Personnel Expenses by Nature:**

|                                  | <b>December 31,</b> |               |
|----------------------------------|---------------------|---------------|
|                                  | <b>2022</b>         | <b>2021</b>   |
| Wages and salaries               | 14,802              | 18,017        |
| Social security contributions    | 3,206               | 8,630         |
| Expenses for pension commitments | 943                 | 1,366         |
| Share-based payments             | 5,026               | 3,122         |
| <b>Total</b>                     | <b>23,977</b>       | <b>31,135</b> |

The decrease in personnel expenses is mainly due to a decrease in headcount as well as accrued bonus, retention measures as part of the global restructuring plan.

**Note 16 Income Tax**

**Reconciliation between the Effective and Nominal Income Tax Expense**

The following table shows the reconciliation between the effective and nominal tax expense at the nominal standard French rate 25 % as of December 31, 2022 and 26.5 % as of December 31, 2021 (excluding additional contributions):

|   | <b>December 31,</b> |             |
|---|---------------------|-------------|
|   | <b>2022</b>         | <b>2021</b> |
| (Loss) before taxes   | ( 96,204)           | ( 98,189)   |
| Theoretical company tax rate  | 25,00%              | 26,50%      |
| Nominal tax expense   | 24,051              | 26,020      |
| <i>Increase/decrease in tax expense arising from:</i>               |                     |             |
| Research tax credit   | 1,430               | 1,990       |
| Share-based compensation  | ( 784)              | ( 104)      |
| Other permanent differences   | ( 100)              | ( 86)       |
| Non recognition of deferred tax assets mainly related to tax losses | ( 24,746)           | ( 25,882)   |
| Other differences   | 79                  | ( 1,557)    |
| Effective tax expenses—current                                      | ( 70)               | 381         |
| Effective tax expenses—deferred                                     | —                   | —           |
| Effective tax rate  | ( 0.07)%            | 0.39%       |

**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:

|                                  | <b>December 31,</b> |                |
|----------------------------------|---------------------|----------------|
|                                  | <b>2022</b>         | <b>2021</b>    |
| <b>Deferred tax assets:</b>      |                     |                |
| Net operating loss carryforwards | 273,964             | 263,086        |
| Share-based compensation         | 1,102               | 5,521          |
| Personnel-related accruals       | 389                 | 376            |
| Pension retirement obligations   | 197                 | 252            |
| Leases                           | 6                   | 518            |
| Other                            | 5,248               | 2,760          |
| <b>Total deferred tax assets</b> | <b>280,907</b>      | <b>272,513</b> |
| Less: Valuation allowance        | ( 280,907)          | ( 272,513)     |
| <b>Net deferred tax assets</b>   | <b>—</b>            | <b>—</b>       |

**Note 17 Commitments**

**Purchase Obligations**

The Company has signed agreements with several contract research organizations (CRO) and part of the ongoing clinical studies for Viaskin<sup>™</sup> Peanuts and Viaskin<sup>™</sup> Milk products. As of December 31, 2022, expenses associated with the ongoing trials amounted globally to \$ 161.6 million, and we had non-cancellable contractual obligations with CRO until year ended 2025 amounting to \$ 48.7 million.

**Letter of Credit and Collateral**

A letter of credit was signed by the Company in May 2017 for \$ 0.3 million to secure the lease of its premises of its United States subsidiary in New York. A collateral of the same amount was signed in order to pledge against this letter of credit.

A Certificate of Deposit, for an initial amount of \$ 0.25 million was signed in order to guarantee an American Express credit cards program in the United States.

In 2015, the Company took a term deposit for a sum of € 0.23 million (equivalent to \$ 0.24 million at closing exchange rate).

**Note 18 Relationships with Related Parties**

The compensation amounts for 2022 presented below, which were awarded to the Directors and Officers of the Company totaled \$ 8 million. The recipients of this compensation are "related parties" under applicable French law and may not be considered executive officers or related parties under comparable SEC and Nasdaq rules and regulations applicable to the Company.

|                          | <u>December 31</u> |              |
|--------------------------|--------------------|--------------|
|                          | <u>2022</u>        | <u>2021</u>  |
| Short-term benefits      | 4,625              | 5,128        |
| Post-employment benefits | 33                 | 67           |
| Termination benefits     | 24                 | 280          |
| Share-based payments     | 3,355              | 1,556        |
| <b>Total</b>             | <b>8,037</b>       | <b>7,031</b> |

The methods for the valuation of the benefit related to share-based payments are presented in Note 12 Share-Based Payments.

Amounts payable to related parties as of December 31, 2022 and 2021 are as follows:

|                     | <u>December 31</u> |              |
|---------------------|--------------------|--------------|
|                     | <u>2022</u>        | <u>2021</u>  |
| Compensation        | 2,009              | 1,820        |
| Pension obligations | 83                 | 156          |
| <b>Total</b>        | <b>2,092</b>       | <b>1,976</b> |

**Note 19 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, 2022 and 2021, 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.

[Table of Contents](#)

The computations for basic and diluted loss per share were as follows (in thousands of U.S. Dollars except share and per share data):

|  | <u>December 31,</u> |               |
|--|---------------------|---------------|
|  | <u>2022</u>         | <u>2021</u>   |
| Net loss   | (96,274)            | (97,809)      |
| Weighted average number of ordinary shares   | 77,384,133          | 54,916,937    |
| <b>Basic and diluted net loss per share attributable to ordinary shareholders (\$/share)</b> | <b>(1.24)</b>       | <b>(1.78)</b> |

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:

|                        | <u>December 31,</u> |             |
|------------------------|---------------------|-------------|
|                        | <u>2022</u>         | <u>2021</u> |
| Non-employee warrants  | 251,693             | 256,693     |
| Employee warrants      | —                   | —           |
| Stock-options          | 5,313,169           | 3,631,210   |
| Restricted stock units | 1,618,778           | 1,240,520   |
| Prefunded warrants     | 28,276,331          | —           |

**Note 20 Events after the Close of the Fiscal Year**

There are no significant events that require adjustments or disclosure in the consolidated financial statements.

BY-LAWS

*(updated by decision of the CEO on November 28, 2022)*

DBV Technologies  
Limited Company with share capital of €9,413,714.50  
177-181 avenue Pierre Brossolette - 92120 Montrouge, France  
Nanterre Trade and Companies Register No. 441 772 522

---

**I. - CHARACTERISTIC FEATURES OF THE COMPANY****Article 1 - Form**

The Company was incorporated in the form of a French Limited Company ( Société Anonyme) with a Board of Directors.

**Article 2 - Name**

The name of the Company is: "DBV Technologies"

**Article 3 - Registered office**

The registered office is located at: 177-181 avenue Pierre Brossolette - 92120 Montrouge, France

**Article 4 - Corporate Purpose**

The Company's corporate purpose in France and in all countries is:

- the development of any innovative medical products, including any drugs, or diagnostic or treatment products;
- the study, research, development, industrial manufacturing, and marketing of said products;
- the use and development of any patents or licenses relating to these products, and generally speaking any commercial, investment or real estate, financial or other transactions that are directly or indirectly related to the corporate purpose in whole or in part, or to any other similar or related purpose, and that may promote the operation and commercial development of the Company.

**Article 5 - Term**

The Company's term is ninety-nine years as from its registration in the Trade and Companies Register.

**Article 6 - Share capital**

The share capital has been set at €9,413,714.50.

It is divided into 94,137,145 ordinary shares with a par value of 10-euro cents (60.10) each. All of the shares have been fully subscribed, and their full amount paid up in cash.

**Article 7 - Changes to the share capital**

I. The share capital may be increased either via the issue of new shares, or by increasing the par value of the existing shares.

---

The new shares will be paid for in cash, or via a contribution in kind, offset against liquid and due receivables, or via the incorporation of profits, reserves, or share premiums into the share capital, either as the result of a merger or demerger, or following the exercise of a right attached to transferable securities granting entitlement to the share capital, including payment of the corresponding amounts, where applicable.

The new equity securities will be issued either at their par value, or at that amount plus a share premium.

Only the Extraordinary General Meeting of Shareholders has the power to decide on increasing the share capital, based on a report from the Board of Directors containing the disclosures required by law.

However, the Extraordinary General Meeting of Shareholders may delegate this power to the Board of Directors under the conditions determined by law. The Board of Directors has the requisite powers to perform a capital increase in one or several installments, to determine its terms and conditions, to record its completion, and to amend the By-Laws accordingly within the limits of the powers so granted by the Extraordinary General Meeting of Shareholders.

If the General Meeting of Shareholders decides to increase the share capital, it may delegate the powers required to perform the transaction to the Board of Directors.

If a delegation of power or of authority is used, the Board of Directors will draw up a supplementary report at the next Ordinary General Meeting of Shareholders.

If the capital increase is performed via the incorporation of profits, reserves, or share premiums, the Extraordinary General Meeting of Shareholders will take decisions under the quorum and majority conditions provided for Ordinary General Meetings of Shareholders. In this case, it may decide that rights amounting to fractional shares may neither be traded nor transferred, and that the corresponding equity securities must be sold. The proceeds from the sale will be allocated to the holders in proportion to their rights.

A capital increase by increasing the par value of the shares can only be decided with the shareholders' unanimous consent, except if it results from the incorporation of profits, reserves, or share premiums into the share capital.

Shareholders will have a preferential right to subscribe to the cash shares issued in order to perform a capital increase, in proportion to the number of shares that they hold. The shares purchased as a result of exercising this right will be shares in the same class as the one for the shares giving rise to said right, together with the shares resulting from the purchase of other transferable securities than shares.

The shareholders may sell all or some of their subscription rights throughout the subscription period. These rights will be tradable if they are stripped from shares that are themselves tradable. Otherwise, they may be sold under the same conditions as the actual shares.

Shareholders may waive their preferential subscription right on an individual basis.

The Extraordinary General Meeting of Shareholders that decides on the capital increase may waive the preferential subscription right under the conditions and limits determined by law, and rule to that effect on the reports prepared by the Board of Directors and the Statutory Auditors under the conditions determined by the laws and regulations in effect.

If the Extraordinary General Meeting of Shareholders, or the Board of Directors in the event of a delegation of authority, has expressly decided to do so, any shares that have not been subscribed on an irrevocable basis will be allotted to shareholders who subscribed to a higher number of shares on a revocable basis than the number to which they were able to subscribe on a preferential basis, in proportion to the subscription rights that they hold, and within the limits of their request, in any event.

If, for any reason, subscriptions have not absorbed the full amount of the capital increase, the Board of Directors may use the options provided for below, or only some of them, in the order that it determines:

- (i) limiting the capital increase to the amount of the subscriptions, subject to the general condition that it amounts to at least three quarters of the increase decided upon, and that this option was not expressly excluded by the Extraordinary General Meeting of Shareholders at the time of issue;
- (ii) allocating the balance of the shares if the Extraordinary General Meeting of Shareholders has not decided otherwise;
- (iii) opening the subscription process to the public if the Extraordinary General Meeting of Shareholders has expressly authorized it.

If subscriptions have not absorbed the entire capital increase following the exercise of these options, or three-quarters of the increase in the case provided for under (i) above, the capital increase will not be performed.

However, the Board of Directors may automatically limit the capital increase to the amount raised in all cases where the unsubscribed shares account for less than 3% of the capital increase.

In the event of a capital increase with or without preferential subscription rights, the Extraordinary General Meeting of Shareholders may provide that the number of securities may be increased by up to 15% of the initial issue, at the same price as the one used for the initial issue within a period of thirty days following the close of the subscription period.

If the capital increase creates fractions of shares, shareholders who have an insufficient number of subscription or allotment rights must make arrangements to purchase or sell the rights required to obtain the delivery of a whole number of new shares.

**II. The Extraordinary General Meeting of Shareholders (or the Board of Directors in the event of a delegation of authority) may also authorize or decide on a capital decrease, subject to the rights of creditors, where applicable.**

Decreasing the share capital below the legal limit can only be decided under the condition precedent of a capital increase intended to return the share capital to an amount that is at least equal to the minimum legal threshold, unless the Company turns itself into a company with another legal form. Otherwise, any interested party may apply to the courts to have the Company wound up. The court may not order the Company to be wound up if the amount of the share capital has been restored to the statutory minimum by the day when it rules on the substance of the case.

**Article 8 - Financial year**

The financial year runs from January 1 to December 31.

**II. - ADMINISTRATION OF THE COMPANY**

**Article 9 - Executive Management exercise method**

The executive management of the Company is the responsibility either of the Chairman of the Board of Directors or of another individual appointed by the Board of Directors bearing the title of Chief Executive Officer.

The Board of Directors chooses between the two Executive Management exercise methods based on the unanimous vote of all of its members.

Where responsibility for the Company's Executive Management is held by the Chairman of the Board of Directors, the following provisions concerning the role of Chief Executive Officer apply.

---

#### **A. The Board of Directors**

##### **Article 10 - Composition of the Board of Directors**

The Company is governed by a Board of Directors that consists of between 3 and 18 directors.

The Directors are appointed by the General Meeting of Shareholders, deliberating under the quorum and majority conditions for Ordinary General Meetings of Shareholders.

The term of office for the Directors appointed during the term of the company is three (3) years. This term expires at the end of the meeting convened to approve the financial statements for the year just ended, and which is held in the year during which their term of office expires.

By way of exception and in order to allow exclusively for the implementation or maintenance of the staggered terms of office of Directors, the ordinary General Meeting of Shareholders may appoint one or more members of the Board for a term of two (2) years or one (1) year.

The Directors may be dismissed at any time and without any good reason by the General Meeting of Shareholders, deliberating under the quorum and majority conditions for Ordinary General Meetings of Shareholders.

The number of Directors aged over eighty cannot exceed one third of the Board members.

##### **Article 11 - Board Discussions**

The Board of Directors meets as often as is required by the Company's interests at the invitation of the Chairman of the Board of Directors, at the registered office or the place specified in the notice of meeting. The invitation may be issued by any means five days in advance; it may also be issued orally and immediately if all of the Directors and non-voting Board members agree.

The Board of Directors may also make decisions by written consultation of the directors under the conditions provided by law.

If it has not met for over two months, at least one quarter of the members of the Board of Directors may ask the Chairman to convene the Board based on a determined agenda. The Chief Executive Officer or a Director may also ask the Chairman to convene the Board of Directors based on a determined agenda. The Chairman will be bound by any such requests.

An attendance register will be kept, and minutes will be drawn up following each meeting. The Board may only validly take decisions if at least half of its members are present.

Except where the choice of the method for exercising Executive Management is concerned, decisions will be taken based on a majority vote of the Directors present or represented. The Chairman will have a casting vote in the event that the vote is split.

The Directors and any individuals asked to attend the Board of Directors' meetings are required to exercise discretion with respect to information of a confidential nature, and which is provided as such by the Chairman of the Board of Directors.

##### **Article 12 - The Board's powers**

The Board of Directors determines the Company's guidelines, and ensures their implementation. Subject to the powers specifically assigned to General Meetings of Shareholders, and within the limits of the corporate purpose, the Board will deal with any matter involving the proper operation of the Company, and settle any matters concerning it through its discussions.

---

The Board of Directors carries out the controls and verifications that it considers appropriate. Every Director will receive all of the information required to fulfill their assignment, and may ask for the disclosure of any documents that they consider useful.

**Article 13 - The Chairman of the Board of Directors**

The Board of Directors elects a Chairman, who must be a private individual, from among its members, and determines their remuneration, in accordance with applicable law. The Chairman is appointed for a period that may not exceed the length of their term of office as a Director. They are eligible for reelection. The Board of Directors may dismiss the Chairman at any time. Any provisions to the contrary will be considered void.

No one aged 75 or over may be appointed as Chairman. If the incumbent Chairman reaches this age during a financial year, their duties will automatically end following the Ordinary General Meeting of Shareholders convened to approve the financial statements for that financial year.

The Chairman organizes and directs the work undertaken by the Board, and accounts for it at the General Meeting of Shareholders. They ensure that the Company's bodies operate properly, and especially that the Directors are in a position to fulfill their assignment.

**Article 14 - Non-Voting Board Members**

The General Meeting of Shareholders may appoint one or two non-voting Board members for the Company who are private individuals, regardless of whether they are shareholders; they will be aged 65 at most on the day of their appointment.

Non-voting Board members are appointed for a period of two (2) years. Their assignment ends after the General Meeting of Shareholders that has approved the financial statements for the year just ended, and held in the year during which their term of office expires.

Non-voting Board members do not receive any remuneration. They may receive allowances determined by the Board of Directors in order to reimburse the expenses that they are required to incur as part of the normal performance of their duties. If the Board delegates a specific assignment to the non-voting Board members or to one of them, they may allocate them an allowance in proportion to the importance of the assignment entrusted to them, as well as a budget for performing said assignment. Non-voting Board members are invited to all of the Board of Directors' meetings and to all of the General Meeting of Shareholders, and take part in the discussions in an advisory capacity. Non-voting Board members perform a general and permanent advisory and supervisory role at the Company. However, they may not interfere in the management of the Company under any circumstances, or, in general, replace its legal bodies.

**B. The Executive Management**

**Article 15 - Chief Executive Officers and Deputy Chief Executive Officers**

The executive management of the Company is the responsibility of a private individual appointed by the Board of Directors bearing the title of Chief Executive Officer, under the Company's responsibility.

The Board of Directors may appoint one or more private individuals responsible for assisting the Chief Executive Officer, who will bear the title of Deputy Chief Executive Officer, on the recommendation of the Chief Executive Officer. The number of Deputy Chief Executive Officers cannot exceed five.

The Chief Executive Officer may be dismissed by the Board of Directors at any time. The same applies to the Deputy Chief Executive Officers, on the recommendation of the Chief Executive Officer. If the dismissal is not on justified grounds, it may result in the payment of damages and interest.

Where the Chief Executive Officer ceases, or is otherwise prevented from performing their duties, the Deputy Chief Executive Officers will retain their positions and their assignments until a new Chief Executive Officer is appointed, unless the Board decides otherwise.

---

The Board of Directors determines the compensation paid to the Chief Executive Officer and the Deputy Chief Executive Officers, in accordance with applicable law.

**Article 16 - Powers of the Chief Executive Officer and Deputy Chief Executive Officers**

The Chief Executive Officer is granted very extensive powers to act in the Company's name in all circumstances. They exercise the powers within the limit of the corporate purpose, and subject to those that the law and these By-Laws expressly assign to General Meeting of Shareholders and to the Board of Directors.

They represent the Company in its dealings with third parties. The Company will be committed even by the Chief Executive Officer's actions that do not relate to the corporate purpose, unless it proves that the third party was aware that the action exceeded that purpose, or could not ignore this fact in view of the circumstances. The sole publication of the By-Laws does not amount to sufficient proof.

The Board of Directors determines the scope and term of the powers granted to the Deputy Chief Executive Officers, with the Chief Executive Officer's consent. The Deputy Chief Executive Officers have the same powers as the Chief Executive Officer where third parties are concerned.

**III. - GENERAL MEETING OF SHAREHOLDERS**

**Article 17 - General Meeting of Shareholders**

The duly constituted General Meeting of Shareholders represents the entire body of shareholders.

Its decisions, which are taken in accordance with the law and the By-Laws, are binding on all of the shareholders, even if they are absent, disagree, or are incapable.

There are three forms of meetings, depending on the purpose of the resolutions put forward:

- Ordinary General Meetings;
- Extraordinary General Meetings;
- Special Meetings that bring together the holders of shares in a given class.

**Article 18 - Invitations**

The Meetings are convened by the Board of Directors. They may also be convened by the Statutory Auditor or by a court representative, under the conditions and in accordance with the procedures provided for by law.

Meetings are convened by the liquidator(s) during the liquidation period.

The Meetings are held at the registered office or at any other location specified in the notice of meeting.

A notice of meeting is published in the *Bulletin des Annonces Légales Obligatoires* (French Official Gazette, or *BALO*) at least thirty-five days before a Meeting is held. In addition to the information relating to the Company, the notice specifies the agenda for the Meeting, and the wording of the draft resolutions that will be put forward. Requests to enter points or draft resolutions on the agenda must be addressed to the Company under the conditions provided for by the regulations in effect.

The Meetings are held at the registered office or at any other location specified in the notice of meeting.

---

Subject to specific legal provisions, the invitation is issued at least fifteen days before the date of the Meeting by a notice inserted in a legal gazette published in the Department where the registered office is located, as well as in the *BALO*.

However, individuals who have held registered shares for at least one month at the date of the last published notice of meeting must be invited on an individual basis, via an ordinary letter (or via registered letter if they make the request and advance the related cost) sent to their last known address. This invitation may also be forwarded via means of electronic telecommunication, instead of by letter, to any shareholder who makes the request beforehand via registered letter with acknowledgment of receipt, in accordance with the legal and regulatory requirements, and provides their email address. The shareholder may expressly ask the Company for the aforementioned means of telecommunication to be replaced by a letter in the future, via registered letter with a request for acknowledgment of receipt.

The notice of meeting must also specify the conditions under which shareholders may vote by post, and the places where, and terms and conditions according to which, they may obtain postal vote forms.

Where applicable, the notice of meeting may be sent with a proxy form and a postal vote form under the conditions specified in Article 21. I of these By-Laws, or only with a postal vote form, under the conditions specified in Article 21. II of these By-Laws.

Where a Meeting has been unable to take decisions as a result of failing to achieve the quorum required, a second Meeting will be convened, subject to specific legal provisions, at least ten days in advance, in the forms provided for by the regulations in effect.

#### **Article 19 - Agenda**

The agenda for Meetings will be prepared by the person convening the meeting.

One or several shareholders, who represent at least the percentage of the share capital specified by law, and acting in accordance with the legal conditions and timeframes, have the option to request the inclusion of points or draft resolutions on the agenda for the Meeting, via registered letter with a request for acknowledgment of receipt.

The Meeting may not discuss an issue that has not been entered on the agenda, which cannot be altered at the time of the second invitation. However, it may dismiss one or several members of the Board of Directors, and replace them in all circumstances.

#### **Article 20 - Shareholders' attendance at the Meetings**

Any shareholder has the right to attend the Meetings and to participate in the discussions

- (i) either in person; or
- (ii) by granting a proxy to any private individual or legal entity of their choice; or
- (iii) by sending a proxy to the Company with no specified mandate; or
- (iv) by voting by post; or
- (v) via video-conference, or via another means of telecommunication that complies with the applicable legal and regulatory provisions.

Attendance at General Meetings of Shareholders in any form is conditional on registering or entering the shares under the conditions and according to the timeframes provided for by the regulations in effect.

The final date for returning postal vote forms is determined by the Board of Directors, and announced in the notice of meeting published in the *BALO*. This date cannot be less than three days before the Meeting.

---

Shareholders who have voted by post will no longer have the option to take part in the Meeting directly, or to be represented by a proxy.

In the event that the proxy form and the postal vote form are returned by post, the proxy form will be taken into consideration, subject to the votes expressed in the postal vote form.

**Article 21 - Shareholder representation**

I. Any shareholder may have themselves represented at Meetings by any private individual or legal entity of their choice, via a proxy form sent to them by the Company:

- either at their request sent to the Company via any means. This request must be received at the registered office at least five days before the Meeting;
- or at the Company's initiative.

The proxy granted by a shareholder in order to have themselves represented at a Meeting will be signed by the latter, via a secure electronic signature process, where applicable, or via any other reliable identification process that guarantees their link to the deed to which it is attached.

The proxy may be revoked in the same way as the proxies required to appoint a representative.

All of the documents and information provided for by the regulations in effect must be enclosed with any proxy form sent to shareholders by the Company for each Meeting.

The proxy granted by a shareholder will only be valid for a single Meeting, or for any successive meetings convened with the same agenda. It may also be granted for two Meetings, one of which is Ordinary, and the other one of which is Extraordinary, and which are held on the same day, within a period of fifteen days.

II. Any shareholder may vote by post using a voting form sent to them by the Company

- at their request, and addressed in writing. This request must be deposited with or reach the registered office at least six days before the date of the Meeting, or
- at the Company's initiative, or
- as an appendix to a proxy vote form, under the conditions provided for by the regulations in effect.

All of the documents and information provided for by the regulations in effect must be attached to any postal vote form sent to shareholders by the Company for each Meeting.

The postal vote form sent to a shareholder will only be valid for a single Meeting or for successive Meetings convened with the same agenda.

**Article 22 - Attendance sheet**

An attendance sheet containing the information specified by law will be kept at each Meeting.

This attendance sheet, duly initialed by the shareholders present and the proxies, and the shareholders attending via video-conference or another means of telecommunication, in accordance with the legal and regulatory requirements, and to which the powers granted to each representative are appended, together with the postal voting forms, will be certified as accurate by the Meeting Bureau.

The Meetings will be chaired by the Chairman of the Board of Directors. Otherwise, the Meeting will elect its own Chairman.

The tellers' duties will be performed by two shareholders who are present and agree to do so, and who represent the highest number of votes, both on their own behalf and as proxies.

---

The Bureau formed in this way will appoint a secretary, who may be chosen from outside the shareholders.

**Article 23 - Quorum**

In Ordinary and Extraordinary General Meetings of Shareholders, the quorum will be calculated on the basis of all of the shares that make up the share capital and, in Special General Meetings of Shareholders, of all the shares in the class in question, minus any shares to which no voting rights are attached, in accordance with the provisions of the law.

The voting right attached to the shares is proportional to the percentage of the total share capital that they represent. Each equity share or dividend share will grant entitlement to one vote. Fully paid-up shares for which proof can be provided that they have been registered in the name of the same shareholder for at least two years do not benefit from double voting rights.

In the event of a postal vote, only the forms filled in and received by the Company at least three days before the Meeting is held will be taken into account.

Forms not indicating a vote or expressing an abstention are not considered as expressed votes.

**Article 24 - Minutes**

The decisions taken at the Meetings will be recorded in minutes that are drawn up in a special ledger held at the registered office, and signed by the members of the Bureau.

Copies or excerpts of the minutes of the decisions will be certified either by the Chairman of the Board of Directors or by the Meeting Secretary. They will be validly certified by the liquidator(s) in the event of liquidation proceedings.

**Article 25 - Disclosure of documents**

Any shareholder has the right to obtain disclosure of, and the Board of Directors is required to send or make available to them, the documents required to enable them to form an opinion in full knowledge of the facts, and to make an informed judgment on the Company's management and operations.

The nature of these documents, and the conditions for sending them or making them available to the shareholders are determined by the regulations in effect.

Every shareholder or their representative may seek the assistance of an expert registered on one of the lists drawn up by the courts, in order to exercise their right of disclosure.

The exercise of the right of disclosure entails the right to take copies, except where records are concerned.

**Article 26 - Ordinary General Meeting of Shareholders**

The Ordinary General Meeting of Shareholders takes all of the decisions that exceed the powers of the Board of Directors and which do not fall within the remit of the Extraordinary General Meeting of Shareholders.

The Meeting is convened at least once a year, within a period of six months following the end of each financial year, in order to approve the financial statements for that year, subject to this period being extended by an order from the Presiding Judge of the Commercial Court ruling at the request of the Board of Directors.

The Meeting is convened on an extraordinary basis every time that this appears to be in the Company's interests.

---

When convened for the first time, the Ordinary General Meeting of Shareholders may only validly deliberate if the shareholders present, represented, or who have voted by post hold at least one fifth of the shares to which voting rights are attached.

No quorum is required if the meeting is convened for a second time and the original agenda has not been amended.

The Ordinary General Meeting of Shareholders decides by a majority of the votes expressed by the shareholders present, represented or voting by mail. The expressed votes do not include those attached to shares for which the shareholder has not taken part in the vote, has abstained or has voted blank or null.

**Article 27 - Extraordinary General Meeting of Shareholders**

Only the Extraordinary General Meeting of Shareholders is authorized to amend all of the provisions of the By-Laws, and to specifically decide on turning the Company into a company with another legal form. It cannot, however increase the shareholders' undertakings, except in the case of transactions resulting from a duly executed reverse share split.

The Extraordinary General Meeting of Shareholders may only validly deliberate if the shareholders present, represented or who have voted by post hold at least one quarter of the shares with voting rights at the time of the first invitation, and one fifth of the shares with voting rights at the time of the second invitation. If the second quorum is not achieved, the second Meeting may be postponed to a date no later than two months after the date on which it was convened.

The Meeting passes resolutions based on a two-thirds majority vote expressed by the shareholders who are present, represented, or have voted by post, or who are attending the Meeting via video-conference or another means of telecommunication, in accordance with the legal and regulatory provisions.

As a legal exemption to the above provisions, a General Meeting of Shareholders that decides on a capital increase via the capitalization of reserves, profits, or share premiums may pass resolutions under the same quorum and majority conditions as an Ordinary General Meeting of Shareholders.

Furthermore, where the Extraordinary General Meeting of Shareholders is required to discuss the approval of a contribution in kind or the granting of a particular benefit, the shares held by the individual making the contribution or the beneficial owner will not be taken into account to calculate the majority. The individual making the contribution or the beneficial owner will not have a vote, either on their own behalf, or as a proxy.

**Article 28 - Special Meeting**

If there are several share classes, no change may be made to the rights attached to shares in one of these classes without a due vote at an Extraordinary General Meeting of Shareholders open to all shareholders and, furthermore, without an equally compliant vote at a Special Meeting open only to the holders of shares in the class in question.

Special Meetings may only validly discuss matters if the shareholders present, represented, who have voted by post, or who are attending the Meeting via video-conference or via another means of telecommunication in accordance with the legal and regulatory provisions, hold at least one third of the shares with voting rights, where an amendment to those rights is planned, on the first invitation, and one fifth of the shares on the second invitation. Otherwise, the second Special Meeting may be postponed to a date no later than two months after the date on which it was convened.

Special Meetings pass resolutions based on a two-thirds majority of the expressed votes of the shareholders present or represented.

---

**IV. - THE COMPANY'S SECURITIES****Article 29 - Payment for the shares**

At least 25% of the par value of shares subscribed in cash must be paid at the time of subscription, together with the full share premium, where applicable.

The balance must be paid in one or several installments, as called by the Board of Directors, and within a period of five years from the date on which the capital increase was finalized.

Calls for funds are made known to the shareholders via a notice published in the *BALO* fifteen (15) days in advance.

If the shareholder does not make the required payments on the amount of the shares to which they have subscribed at the times determined by the Board of Directors, these payments will automatically bear interest payable to the Company at the legal rate determined in Article L. 313-2 of the French Monetary and Financial Code, as from the end of the month following the date when they are due, without any requirement for a court application or letter of notice. Furthermore, shares for which the required payments have not been made at the end of a period of 30 days as from the sending of a letter of notice to the defaulting shareholder, to which no reply has been received, will no longer grant the right to attend General Meetings of Shareholders and to vote at those Meetings, and will be deducted from the quorum calculation. The right to dividends, and the preferential right to subscribe to capital increases attached to the shares will be suspended. These rights will be recovered once the capital and interest amounts due have been paid. The shareholder may then request the payment of dividends that have not expired, and exercise their preferential subscription right, if the determined timeframe for exercising that right has not expired.

The share capital must be fully paid up before any issue of new shares to be paid for in cash.

**Article 30 - Form of the shares - Management of the securities accounts**

The shares may be in registered or bearer form, if the legislation allows, depending on the shareholder's choice.

Issued shares give rise to a registration in individual accounts in the name of each shareholder opened by the Company or any authorized intermediary. These accounts are held under the conditions and in accordance with the procedures provided for by the legal and regulatory provisions.

In order to identify the owners of bearer shares, the company may, under the conditions provided for by the legal and regulatory provisions in force, request, at any time, information concerning the owners of its shares and securities conferring immediate or future voting rights at its own General Meetings of Shareholders.

**Article 31 - Transfer of the shares**

Shares registered on an account are transferred from account to account.

Cash shares are freely tradable as from the completion of the capital increase. Shares resulting from contributions are freely tradable as from the completion of the capital increase, i.e. the date of the Meeting or of the meeting of the Board of Directors acting on a delegation of authority, which approved the contributions, in the event of a contribution in kind during the term of the company.

The transfer of ownership will result from their registration on the purchaser's account, on the date and under the conditions determined by law and the applicable regulations, where applicable.

The shares will be freely tradable, subject to the provisions provided for by law.

**Article 32 - Crossing of thresholds**

Any private individual or legal entity referred to in Articles L. 233-7, L. 233-9, and L. 223-10 of the French Commercial Code who comes to directly or indirectly hold a number of shares representing a percentage of the Company's share capital or voting rights higher than or equal to 2.5% or a multiple of that percentage, either on a stand-alone basis or in concert, must inform the Company of the total

---

number of shares, voting rights, and securities granting access to the share capital or to voting rights immediately or in the future that they hold, via registered letter with a request for an acknowledgment of receipt sent to the registered office within a period of four trading days, prior to the market close as from the point when they crossed said percentage threshold(s).

The disclosure obligation provided for above also applies under the same conditions when each threshold mentioned above is crossed downwards.

If they have not been reported under the conditions specified above, shares or voting rights that exceed the percentage that should have been reported will be stripped of their voting rights at General Meetings of Shareholders at any Meeting that may be held until the expiry of a two-year period following the date when the notice of interest was made compliant, in accordance with Article L. 233-14 of the French Commercial Code, if a failure to report has been observed, and if one or several shareholders holding an interest of at least 2.5% have made a request recorded in the minutes of the General Meeting of Shareholders.

The above reports will apply notwithstanding the reports on the crossing of thresholds provided for by the legal or regulatory provisions in effect.

#### **Article 33 - Rights and obligations attached to the shares**

Each share entitles the holder to a share in the Company's profits and assets, in proportion to the amount of capital that it represents.

Furthermore, each share entitles the holder to vote and be represented at General Meetings of Shareholders under legal and statutory provisions.

Shareholders will only be liable up to the amount of the par value of the shares that they hold; any calls for funds above that amount are prohibited.

Ownership of a share automatically entails adherence to the Company's By-Laws and to the decisions of the General Meeting of Shareholders.

Heirs, creditors, assigns, or other representatives of a shareholder will not be entitled to request seizure of the Company's assets or securities, or ask for them to be shared out or sold at auction, nor interfere in administrative acts relating to the Company in order to exercise their rights; they must refer to the company records and to the resolutions of the General Meeting of Shareholders.

Whenever it is necessary to hold several shares in order to exercise a given right, such as in the case of an exchange, reverse share split or allotment of shares, or an increase or decrease in the share capital, or a merger or other corporate transaction, the holders of single shares, or of a lower number of shares than required, may only exercise these rights if they personally arrange for the consolidation, and potentially the purchase or sale of the shares required.

However, in the event of the exchange of securities following a merger or demerger transaction, a capital decrease, a reverse share split or share split, and the mandatory conversion of bearer shares to registered shares, or of the distribution of securities charged to the reserves relating to a capital decrease, or the distribution or allotment of bonus shares, based solely on a decision by the Board of Directors, the Company may sell securities that the beneficiaries have requested to be delivered to them, as long as it has carried out the publication formalities provided for in the regulations at least two years beforehand.

As from the sale, the old securities or the old rights to distributions or allotments will be canceled, as and when required, and their holders will only be able to claim the cash allocation of the net proceeds of the sale of the unclaimed securities.

#### **Article 34 - Beneficial & Bare ownership**

The shares are indivisible as regards the Company.

---

Joint owners of shares are required to have themselves represented to the Company by just one of them, who will be considered as the sole owner, or by a single proxy; in the event of disagreement, the single proxy may be appointed by a court at the request of the first joint owner to do so.

Unless the Company has been notified of an agreement to the contrary, the beneficial owners of shares will validly represent the bare owners with the Company. Voting rights will be held by the beneficial owner at Ordinary General Meetings of Shareholders and by the bare owner at Extraordinary General Meetings of Shareholders.

Unless otherwise agreed between the parties, the preferential subscription right attached to securities belongs to the bare owner where the shares are encumbered by a usufruct interest.

#### **V. - COMPANY FINANCIAL STATEMENTS**

##### **Article 35. - Preparation and approval of the company financial statements**

a) The Board of Directors will draw up an inventory and the annual financial statements at the end of each financial year, and will then prepare the management report.

Where applicable, the Board of Directors will prepare and publish the consolidated financial statements, together with the report regarding the management of the Group.

b) The Ordinary General Meeting of Shareholders will approve the annual company financial statements within a period of six months following the financial year-end, after familiarizing itself with the management report and the report prepared by the Statutory Auditors; the consolidated financial statements and the report regarding the management of the Group will be presented at that Meeting, if required.

All information measures will be taken in compliance with the law and the regulations.

##### **Article 36 - Audit of the financial statements**

The financial statements will be audited by one or several incumbent, and, where applicable, alternate Statutory Auditors, under the conditions determined by Articles L. 225-218 of the French Commercial Code.

##### **Article 37 - Allocation of the amounts available for distribution**

Following the approval of the financial statements, and the recording of the existence of amounts available for distribution, the Ordinary General Meeting of Shareholders will determine the share of these amounts allotted to the shareholders in the form of a dividend; this dividend will be charged to the distributable profit for the year as a priority.

The procedures for paying the dividends or interim dividends are determined by the General Meeting of Shareholders.

Write-down differences are not available for distribution.

If required, the Meeting will allocate the non-distributed portion of the profit for the financial year available for distribution in the proportions that it determines, either to one or several reserves, which may be general or special, which remain at its disposal, or to the "retained earnings" account.

Any losses will be carried forward, unless the Meeting decides to offset them against existing reserves.

---

**VI. - LIQUIDATION OF THE COMPANY****Article 38 - Liquidation**

Once it has been wound up, the Company will be liquidated under the conditions determined by the French Commercial Code.

Unless the Ordinary General Meeting of Shareholders decides otherwise, the liquidator or liquidators will pursue any ongoing business until it is completed.

The net proceeds of the liquidation, following the settlement of the liabilities and payroll expenses, and repayment to the shareholders of the non-amortized par value of their shares, will be divided between the shareholders, taking the rights of the different share categories into account, where applicable.

**VII - MISCELLANEOUS ITEMS****Article 39 - Powers**

All powers will be granted to the bearers of original copies of these By-Laws, or of copies or excerpts certified as original, in order to carry out all formalities.



**DBV TECHNOLOGIES  
PLAN RULES OF THE  
2022 STOCK OPTION PLAN (INTERNATIONAL VERSION)**

**Purpose and background of the Plan:**

DBV Technologies ("DBV Technologies" or the "Company") is granting to its employees options to purchase and/or subscribe shares of DBV Technologies under this 2022 Stock Option Plan (the "Plan"). Through this Plan, employees can become shareholders of DBV Technologies, rewarding their contributions to its development.

The implementation of this Plan is based on the authorization given by the shareholders of the Company at the Annual General Meeting of Shareholders of DBV Technologies held on May 12, 2022, in its 26th resolution, which authorized the Board of Directors to award options to purchase and/or subscribe shares of DBV Technologies (such awards being referred to as "Options") to employees of the Company and its subsidiaries, in accordance with articles L. 225-177 et seq, as well as L. 22-10-56 et seq, of the French Commercial Code. The implementation of this Plan should also comply with articles L. 22-10-8 et seq, as well as L. 22-10-34 of the French Commercial Code.

The grant of Options under this Plan was made on November 21, 2022 (the "Grant Date"), by the Board of Directors of the Company. Each Option entitles its holder to acquire/subscribe to one share of the Company at a preferred exercise price, subject to the satisfaction of a continued employment condition and to the other terms and conditions set forth in this Plan.

This document sets forth the terms of the Plan for participants who are employed by a company of the DBV Technologies Group (as this term is defined below) located outside of France, on the Grant Date.

**1 Participants and number of Options granted to each**

Individuals receiving Options under this Plan ("Participants") are employees and corporate officers of the Company and those companies in which it holds directly or indirectly a majority of the share capital and/or voting rights (together the "Group Companies" or "DBV Technologies Group"). The list of Participants, the number of Options granted to each and the exercise price ("Exercise Price") have been fixed by the Board of Directors on the Grant Date.

Each Option entitles its holder to acquire/subscribe to one share of the Company ("Share") at the Exercise Price, subject to conditions set forth in this Plan.

The Exercise Price is € 3, which is equal to the price of the Shares on Euronext Paris on the Grant Date, which is not less than the average of the share prices quoted over the twenty (20) trading days preceding the Grant Date.



Each Participant will be informed of the grant by a notification letter (which may be sent electronically on the website of the plan administrator mandated by the Company (the "**Plan Administrator**")). The Participant must acknowledge receipt of the notification and accept the grant within 60 days of the date of the notification letter, failing which the Company may cancel the grant, without prior notice or compensation. The acceptance procedure will be set forth in the notification letter. Acceptance of the grant by the Participant will also include an acceptance of its terms and of these Plan rules, including Annex 1.

## 2. Vesting schedule and dates

The Options will vest in installments over a four-year period starting from the Grant Date, according to the schedule set forth below and subject to the satisfaction of the continued employment condition and to the other terms and conditions set forth in this Plan. Such installments are not necessarily equal and may be subject to rounding.

For each Option, the period between the Grant Date and its scheduled "**Vesting Date**" set forth below is referred to as its "**Vesting Period**".

- 25 % of the Options shall be eligible to vest on November 21, 2023, one year following the Grant Date.
- an additional 25 % of the Options shall be eligible to vest on November 21, 2024, two years following the Grant Date.
- an additional 25 % of the Options shall be eligible to vest on November 21, 2025, three years following the Grant Date.
- an additional 25 % of the Options shall be eligible to vest on November 21, 2026, four years following the Grant Date.

In the event that the Participant's employment or corporate office is involuntarily terminated other than for cause within twelve months following the date of the consummation of a takeover leading to a change of control of the Company as defined in Article L. 233-3 of the French Commercial Code, the vesting and exercisability of each of the Participant's Options (including the Options that have not vested) shall be automatically accelerated in full. The Options shall then be exercisable during a 90 day-period starting from the date on which the Participant is notified of his or her termination.

"Cause" as a reason for a Participant's termination of employment shall have the meaning assigned such term in the employment, severance or similar agreement, if any, between such Participant and his or her employer, provided, however that if there is no such employment, severance or similar agreement in which such term is defined, then "Cause"



shall mean any of the following acts by the Participant, as determined by the Company: gross neglect of duty, prolonged absence from duty without the consent of the Company or applicable Group Company, material breach by the Participant of any published Company or applicable Group Company code of conduct or code of ethics; intentionally engaging in activity that is in conflict with or adverse to the business or other interests of the Company or applicable Group Company; or willful misconduct, misfeasance or malfeasance of duty which is reasonably determined to be detrimental to the Company or applicable Group Company. The determination of the Company as to the existence of "Cause" shall be conclusive on the Participant.

### 3. Manner of Exercise

Once vested, the Options can be exercised, on one or more occasions at the Participants' discretion, at any time between the first anniversary date of the Grant Date (included), and the tenth anniversary date of the Grant Date, on November 21, 2032 (included) at midnight Paris Time (the "Exercise Period"), subject to the terms and conditions of this Plan. Thereafter, the Options will automatically lapse.

Each Participant may exercise their Options by (i) giving written notice to the Company specifying the number of Shares with respect to which the Options are being exercised (ii) providing full payment of the aggregate Exercise Price for the number of Shares specified in the notice.

Payment of the Exercise Price for the Shares may be made in cash, by certified or bank check or other instruments acceptable to the Plan Administrator.

The Shares purchased/subscribed upon exercise of the Options shall be transferred to the Participant upon compliance to applicable laws or regulations in connection with such transfer and with the requirements hereof.

In accordance with applicable law, the Board of Directors may suspend for a given period, at its sole discretion, the exercise rights attached to the Options.

### 4. Continued Employment Condition

The vesting and the exercise of each Participant's Options are subject to him or her remaining an employee or executive corporate officer of the Company or another Group Company until the scheduled Vesting Date and, thereafter, until the date of exercise. Such employment must be continuous and without interruption. Exceptions to this condition are set forth below.

If employment or corporate office is terminated or lapses at any time, then any Option that was previously exercisable on or prior to the termination date (the "Termination Date" as defined below) according to the vesting schedule set forth in Article 2, shall then be exercisable during a 90 day-period starting from the Termination Date. After this period the vested Options shall be immediately cancelled without prior notice or compensation.



Any Option that has not vested on or prior to the Termination Date shall also be immediately cancelled without prior notice or compensation.

The Termination Date shall mean the date on which employment or corporate office is terminated or lapses or, if sooner:

- in the event of resignation, the date on which the Company or the applicable Group Company receives the letter of resignation or other written notification of resignation from the Participant or his or her agent;
- in the event of dismissal (or equivalent), the date on which the Company or the relevant Group Company shall inform the Participant in writing of its intention to terminate or not renew the employment relationship or the corporate office;

Employment will also be deemed to be terminated for these purposes if at any time the company employing the Participant or in which he or she holds corporate office shall cease to be a "Group Company" as a result of a reduction in DBV Technologies' stake in such company (share capital and/or voting rights).

##### **5. Exceptions to the Continued Employment condition**

Notwithstanding the provisions of Article 4, an exception to the Continued Employment Condition shall be made in the following cases:

a) Death of the Participant

The Options shall be fully vested and may thereafter be exercised by the Participant's heir(s) for a period of six (6) months from the date of death. The Shares resulting from the exercise of the Options will then be freely transferable.

b) Disability of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, "disability" shall have the meaning provided for under Section 409A of the Internal Revenue Code.

For Participants who are employed by the Company or a French company of the DBV Technologies Group or by any other entity of the DBV Technologies Group which is not a U.S. company, "disability" shall have the meaning provided in the second or third of the categories provided for by Article L. 341-4 of the French Social Security Code.

Following a disability, the Options outstanding and vested on such date according to the vesting schedule set forth in Article 2 shall remain exercisable. The Shares resulting from the exercise of the Options will then be freely transferable. Any Options not vested on or prior to the date of disability shall terminate immediately and be of no further force or effect, without prior notice or compensation.



c) **Retirement of the Participant**

For Participants who are employed by a U.S. company of the DBV Technologies Group, retirement shall mean a termination of continued employment after attainment of age 62.

For Participants who are employed by the Company or a French company of the DBV Technologies Group, retirement shall mean retirement after meeting retirement eligibility in accordance with applicable French law or in an early retirement within the framework of a collective legal or contractual early retirement plan set up by the relevant Group Company.

For Participants employed by a company of the DBV Technologies Group located outside of France or the United States, retirement shall mean retirement after meeting retirement eligibility in accordance with the applicable local law.

Following a retirement, the Participant may retain and exercise any Options that have vested prior to the effective date of retirement. The Participant's Options scheduled to vest on the first scheduled Vesting Date occurring after the effective date of retirement, shall remain eligible to vesting. Options with a subsequent Vesting Date shall be immediately cancelled, without prior notice or compensation. Vested Options may thereafter be exercised by the Participant at any time during the Exercise Period.

In addition to the foregoing, the Board of Directors of the Company may waive the Continued Employment Condition in whole or in part on a case by case basis, in its discretion.

**6. Transfer of shares**

The transfer of the Shares resulting from the exercise of the Options is possible only as from the first anniversary date of the Grant Date (included).

However, any Participant or the heirs or assigned of a deceased Participant as provided by Article 5 above are entitled to transfer the resulting Shares at any time after the acquisition of such Shares.

The exercise of the Options by the Participant and the transfer or sale of the resulting Shares by the Participant must be made in compliance with various provisions aimed at ensuring the transparency and the security of financial markets, and in particular those provisions concerning insider trading. In this regard, periods preceding the publication of the annual and interim financial statements will be fixed and announced by the Company, during which the sale of Shares will be prohibited. Furthermore, the Board of Directors may implement procedures that Participants must follow before selling shares, in order to ensure that they are in not in possession of information liable to block such sale.



More generally, Participants will be required to adhere to the Company's Insider Trading Policy and to applicable French and U.S. federal and state laws.

Notwithstanding anything in this Plan to the contrary, the transfer of any Shares shall be conditioned on compliance with all applicable laws and regulations. The Company shall not be required to transfer Shares in any circumstances that it deems not to be in compliance with such laws and regulations.

If any such law or regulation shall require the Company, or any Participant to take any action in connection with the transfer, the transfer of Shares shall be suspended and deferred until such action shall have been taken.

#### **7. Characteristics of the Shares**

The Shares subscribed by the Participant will be new or existing ordinary shares to be issued by DBV Technologies, at the choice of the Board of Directors of DBV Technologies. In the absence of an express choice before the end of the first anniversary date of the Grant Date, then the Shares will be new shares.

The new Shares issued in favor of some or all the Participants shall have the same rights as those attached to the existing DBV Technologies shares as from their issuance.

#### **8. Adjustment**

In the event of a redemption or reduction of share capital, a change in the allocation of profits, a grant of free shares to all of the shareholders, an increase in share capital by incorporation of reserves, profits or share premium, a distribution of reserves, a share buy-back at a price above the share price on the stock exchange or any issues of equity instruments that includes subscription rights reserved for the shareholders, the Exercise Price and the number of Shares to which an Option gives right will be adjusted in order to take into account such issuance or other capital transaction.

If such a situation is covered by existing law or regulation, such law or regulation shall be applied.

If such a situation is not covered by existing French law or regulation, the General Meeting of Shareholders or the Board of Directors when deciding to proceed with such securities issuance or other modification of the share capital may adopt any adjustment measures necessary to protect the rights of the holders of the Options, using by analogy the rules and regulations which would govern similar cases.

Each Participant will be informed of the practical terms of such an adjustment and of its consequences on his/her award of Options.



#### **9. Compensation Recovery (Clawback)**

Any Shares transferred under this Plan to a Participant who is a current or former executive officer of the Company shall be subject to compensation recovery (clawback) to the extent required by applicable law or regulations and DBV's recovery policy in the event the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirements under the applicable securities laws.

#### **10. Restructuring and mergers**

In accordance with Article L. 228-101 of the French Commercial Code, if the Company is absorbed by another company or merges with one or several other companies resulting in the creation of a new entity, or in case of a demerger (*scission*), the Participants will be entitled to exercise their Options in the company or companies receiving the capital contributions.

#### **11. Social and tax treatment**

The Participant is responsible for making declarations and payments to be made or owed by him/her under applicable law and particularly in respect of his/her tax liabilities. Applicable social security law and tax law vary depending on the country of residence of the Participants.

Each Participant is responsible for inquiring about the social and tax treatment applicable to him /her in his/her country of residence due to the grant or exercise of Options or the issuance or transfer of the resulting Shares.

In the event that, as a result of the grant or exercise of Options or the issuance or transfer of the resulting Shares and, as the case may be, as provided by applicable law, DBV Technologies or a Group Company would have to pay taxes, social security contributions or any other tax or governmental contribution on behalf of the Participant, DBV Technologies reserves the right to delay or prohibit the grant, exercise and/or issuance or transfer of the Shares until such Participant has repaid to DBV Technologies or to the relevant Group Company the amount corresponding to such taxes, social security contributions or any other tax or governmental contribution. DBV Technologies or the relevant Group Company as the case may be, reserves the right (i) to deduct such taxes, social security contributions or any other tax or governmental contribution from the compensation due to the Participant concerned, or (ii) to transfer or sell a sufficient number of shares in order to fulfill the Participant's obligations, the transfer proceeds being directly paid to DBV Technologies or to the relevant Group Company.

#### **12. Limitation of rights**

The Options are not transferrable.



Options do not have any right attached to ordinary shares, including voting rights or rights to dividends. The Participant shall become full owners of the Shares and attached rights only upon exercise of the Options.

The Options are separate from the Participant's employment contract and are not part of it. They are not taken into account to compute termination payments, pensions or any other payments made in the context of employment relationship termination.

None of the provisions which are set out in the Plan constitute an element of the employment contract of a Participant. The rights and obligations deriving from the employment relationship between the Participant and DBV Technologies or a Group Company shall in no way be affected by the Plan from which they are completely distinct. Participation in the Plan shall not confer any right relating to the continuation or creation of any employment relationship or any right upon termination of any such relationship.

**13. Construction of the Plan and governing law**

It will be the responsibility of the Board of Directors to construe the provisions of the Plan, if required, which may delegate this power to the Chief Executive Officer or to the Global Head of Human Resources of the Group.

This Plan is governed and shall be construed in accordance with French law, and any claim relating thereto will be subject to the jurisdiction of the courts within the jurisdiction of the Court of Appeal of Paris. For Participants who are who are employed by a U.S. Company of the DBV Technologies Group, this Plan shall be construed in accordance with Section 409A of the United States Internal Revenue Code.

**14. Modification of the plan**

The terms of this Plan may be amended or supplemented by the Board of Directors (i) if it deems such amendment or supplement to be appropriate and not materially adverse to the interest of the affected Participants or (ii) by mutual agreement with the affected Participants.

More generally, in the event of a change in any legal, regulatory or accounting requirements applicable to the Plan, or any change in the interpretation thereof, in particular with respect to the fiscal or social treatment of any grant or exercise of Options, or delivery of Shares under the Plan, affecting the Company, any Group Company or any Participants, the terms of the Plan may be amended or supplemented by the Board of Directors, in its discretion and in the manner that it deems appropriate, in response to such change. For example, the Board of Directors may choose to shorten or lengthen the Vesting Period, the Exercise Period and/or to introduce a mandatory lock-up period and/or waive or modify any condition to Exercise Conditions and/or introduce new conditions. Furthermore, the Board of Directors may, if it deems the delivery of Shares to any Participant following exercise of Options would be impossible or inopportune, choose to pay instead an amount in cash of equivalent value, net of taxes and social charges. The amount and timing of any such payment would be determined by the Board of Directors.



in its discretion, by reference to the number and timing of any Shares to be otherwise delivered to Participants hereunder following the exercise of Options, to be valued by the Board of Directors on or around the scheduled delivery date, or by reference to an average price over a period preceding such date.

Participants shall not be entitled to any indemnification for any loss of value and/or increased tax or social costs resulting from any such amendments or supplements to the Plan, irrespective of whether such loss or increase is of general application or is specific to them in view of their personal situation.

\*\*\*

Annex 1

**Information Notice on the Protection of Personal Data**

By participating in the Plan, the Participant acknowledges that his/her personal information be subject to electronic data processing carried out under the control of the Company, with the assistance of his/her employer, in accordance with French Law n°78-17 of January 6, 1978 on data processing, data files and individual liberties, the EU Regulation on Data protection (2016/679) of April 27, 2016 (GDPR) and applicable local laws. It shall be implemented on the basis of legitimate interest (Article 6(1)(f) of the GDPR) because it is necessary for the administration of his/her rights under the plan and on for compliance of legal obligations (Article 6(1)(c) of the GDPR), for all purposes relating to the implementation of the Plan, *i.e.*:

- (i) administering and maintaining Participant records.
- (ii) providing information to members of the Group, registrars, brokers or third-party administrators of the Plan.
- (iii) providing information to future purchasers of the Company or of the business in which the Participant works.
- (iv) transferring information about the Participant to France or to another country or territory outside of his/her home country and/or of the European Economic Area that may not provide the same statutory protection for the information as the Participant's home country; and
- (v) complying with legal obligations.

All personal information subject to the electronic data processing is mandatory for the participation to the Plan. All this information will be transmitted (and be transferred to France) to and used for account administration and electronic storage of this data, by the internal departments of the Group in charge of the management of his/her shareholder's account, and to external entities designated to manage the same, and to all persons statutorily or expressly authorized by DBV Technologies or by an employer to hold and process this information (in particular the holder of shareholders accounts), as well as to any future acquirer of DBV Technologies or his/her employing company or the business in which he/she is working within the duration of the Plan. This personal information shall be retained for the time required for the completion of the Plan and for the purposes of the management of the shareholder's account, until he/she sells all his/her DBV Technologies shares under the Plan, and thereafter for archiving purposes until the expiration of the limitation period of any possible litigation relating to the processing of such data.



Every Participant will be able to exercise a right to access, to modify and to rectify, and as well as to delete (once he/she no longer holds any Shares under the Plan) any information relating to him/her. Furthermore, each Participant will have the right to restriction of processing and to object to processing as well as the right to data portability. The right of data portability shall allow the Participant to recover his/her data directly or to transfer them or have them transferred to another data controller (subject to legal limits). According to French law, he/she will have a right to define the directives in relation to the registration, the removal and the communication of his/her personal data after his/her death.

In some countries, local regulations require the express consent of the Participant for the processing and transfer of his/her personal data. In such a case, the Participant's consents, under the acceptance procedure, to the collection, use, storage and transfer of his/her personal data, within the framework of local law. Furthermore, local law may provide that he/she has the right to withdraw his/her consent for the processing of his/her personal data. However, his/her personal data is necessary for the processing of his/her participation to the Plan, the holding of his/her Shares under the Plan and the execution of all operations related to his/her investment. Accordingly, he/she will be able to exercise his/her right to withdraw his/her consent only when all the Shares held under the Plan have been sold.

The Company has appointed a data protection officer, who is responsible for compliance with this notice and can be contacted at the following address: [dataprivity@dbv-technologies.com](mailto:dataprivity@dbv-technologies.com).

The Participant have the right to lodge a complaint with his/her supervisory authority (in France, the supervisory authority is the CNIL), concerning the protection of personal data.



**DBV TECHNOLOGIES**  
**PLAN RULES FOR THE**  
**2022 FREE SHARE PLAN (INTERNATIONAL VERSION)**

**Purpose and background of the Plan:**

DBV Technologies ("DBV Technologies" or the "Company") is granting to its employees a right to receive shares of DBV Technologies for free under this 2022 Free Share Plan (the "Plan"). Through this Plan, employees can become shareholders of DBV Technologies, rewarding their contributions to its development.

The implementation of this Plan is based on the authorization given by the shareholders of the Company at the Annual General Meeting of Shareholders of DBV Technologies held on May 12, 2022, in its 25th resolution, which authorized the Board of Directors to award free shares (such awards being referred to as "**Restricted Stock Units**") to employees of the Company and its subsidiaries, in accordance with articles L. 225-197-1 to L. 225-197-5 as well as L. 22-10-59 et seq. of the French Commercial Code. The implementation of this Plan should also comply with articles L. 22-10-8 et seq. as well as L. 22-10-34 of the French Commercial Code.

The grant of Restricted Stock Units under this Plan was made on November 21, 2022 (the "Grant Date"), by the Board of Directors of the Company. Each Restricted Stock Unit entitles its holder to receive one share of the Company, subject to the satisfaction of a continued employment condition and to the other terms and conditions set forth in this Plan.

This document sets forth the terms of the Plan for participants who are employed by a company of the DBV Technologies Group (as this term is defined below) located outside of France, on the Grant Date.

**1 Participants and number of shares granted to each**

Individuals receiving restricted stock units under this Plan ("Participants") are employees and corporate officers of the Company and those companies in which it holds directly or indirectly a majority of the share capital and/or voting rights (together the "Group Companies" or "DBV Technologies Group"). The list of Participants and the number of Restricted Stock Units granted to each has been fixed by the Board of Directors on the Grant Date.

Each Participant will be informed of the grant by a notification letter (which may be sent electronically on the website of the plan administrator mandated by the Company (the "Administrator")). The Participant must acknowledge receipt of the notification and accept the grant within 60 days of the date of the notification letter, failing which the Company may cancel the grant, without prior notice or compensation. The acceptance procedure will be set forth in the notification letter. Acceptance of the grant by the Participant will also include an acceptance of its terms and of these Plan rules, including Annex 1.



## 2 Vesting schedule and dates

The right to receive Shares under the Restricted Stock Units will vest in installments over a four-year period starting from the Grant Date, according to the schedule set forth below and subject to the satisfaction of the continued employment condition and to the other terms and conditions set forth in this Plan. Such installments are not necessarily equal and may be subject to rounding.

For each Restricted Stock Unit, the period between the Grant Date and its scheduled "Vesting Date" set forth below is referred to as its "Vesting Period".

| <b>Vesting</b>   | <b>Delivery</b>   |
|--|---|
| 25 % of the restricted stock units shall be eligible to vest on November 21, 2023, one year following the Grant Date.                  | The Shares underlying these Restricted Stock Units should be delivered on the first business day following November 21, 2024. |
| an additional 25 % of the restricted stock units shall be eligible to vest on November 21, 2024, two years following the Grant Date.   | The Shares underlying these Restricted Stock Units should be delivered on the first business day following the Vesting Date.  |
| an additional 25 % of the restricted stock units shall be eligible to vest on November 21, 2025, three years following the Grant Date. | The Shares underlying these Restricted Stock Units should be delivered on the first business day following the Vesting Date.  |
| an additional 25 % of the restricted stock units shall be eligible to vest on November 21, 2026, four years following the Grant Date.  | The Shares underlying these Restricted Stock Units should be delivered on the first business day following the Vesting Date.  |

In the event that the Participant's employment or corporate office is involuntary terminated other than for cause within twelve months following the date of the consummation of a change of control of the Company as defined in Article L. 233-3 of the French Commercial Code, the vesting of each of the Participant's Restricted Stock Units (including the Restricted Stock Units that have not vested) shall be automatically accelerated in full and the underlying Shares shall be delivered as soon as practicable thereafter. In the event of change in control occurring prior to the second anniversary of the Grant Date, such delivery shall be made on the first business day following such second anniversary.

"Cause" as a reason for a Participant's termination of employment shall have the meaning assigned such term in the employment, severance or similar agreement, if any, between such Participant and his or her employer, provided, however that if there is no such employment, severance or similar agreement in which such term is defined, then "Cause" shall mean any of the following acts by the Participant, as determined by the Company: gross neglect of duty, prolonged absence from duty without the consent of the Company or applicable Group Company, material breach



by the Participant of any published Company or applicable Group Company code of conduct or code of ethics; intentionally engaging in activity that is in conflict with or adverse to the business or other interests of the Company or applicable Group Company; or willful misconduct, misfeasance or malfeasance of duty which is reasonably determined to be detrimental to the Company or applicable Group Company. The determination of the Company as to the existence of "Cause" shall be conclusive on the Participant.

### 3      **Continued employment condition**

The vesting of each Participant's Restricted Stock Units on their respective Vesting Date is subject to him or her remaining an employee or executive corporate officer of the Company or another Group Company for the full duration of the applicable Vesting Period, up to and including the Vesting Date. Such employment must be continuous and without interruption. Exceptions to this condition are set forth below.

If employment or corporate office is terminated or lapses at any time during the Vesting Period, then all Restricted Stock Units eligible to vest according to the vesting schedule set forth in Article 2 on or after the Termination Date (as defined below) shall be immediately cancelled, without prior notice or compensation.

The Termination Date shall mean the date on which employment or corporate office is terminated or lapses or, if sooner:

- in the event of resignation, the date on which the Company or the applicable Group Company receives the letter of resignation or other written notification of resignation from the Participant or his or her agent.
- in the event of dismissal (or equivalent), the date on which the Company or the relevant Group Company shall inform the Participant in writing of its intention to terminate or not renew the employment relationship or the corporate office.

Employment will also be deemed to be terminated for these purposes if at any time the Company employing the Participant or in which he or she holds corporate office shall cease to be a "Group Company" as a result of a reduction in DBV Technologies' stake in such company (share capital and/or voting rights).

### 4      **Exceptions to the Continued Employment Condition**

Notwithstanding the provisions of Article 3, an exception to the Continued Employment Condition shall be made in the following cases:

#### a) Death of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, the Shares underlying the outstanding Restricted Stock Units shall be delivered within 90 days of the date of death to the Participant's heirs or assignees, or in escrow if they cannot be identified.



For Participants who are employed by the Company or a French company of the DBV Technologies Group or by any other entity of the DBV Technologies Group which is not a U.S. company, the heirs or assignees may request an early delivery of the Shares underlying the outstanding Restricted Stock Units within six (6) months from the date of death of the Participant.

The Shares received will be freely transferable.

b) **Disability** of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, "disability" shall have the meaning provided for under Section 409A of the Internal Revenue Code. Following a disability, the Shares underlying the outstanding Restricted Stock Units shall be delivered within 90 days of notification to the Company.

For Participants who are employed by the Company or a French company of the DBV Technologies Group or by any other entity of the DBV Technologies Group which is not a U.S. company, "disability" shall have the meaning provided in the second or third of the categories provided for by Article L. 341-4 of the French Social Security Code. Following a disability, the affected may request early delivery of the Shares underlying the outstanding Restricted Stock Units. The Shares received will be freely transferable.

c) **Retirement** of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, retirement shall mean a termination of continued employment after attainment of age 62.

For Participants who are employed by the Company or a French company of the DBV Technologies Group, retirement shall mean retirement after meeting retirement eligibility in accordance with applicable French law or in an early retirement within the framework of a collective legal or contractual early retirement plan set up by the relevant Group Company.

For Participants employed by a company of the DBV Technologies Group located outside of France or the United States, retirement shall mean retirement after meeting retirement eligibility in accordance with the applicable local law.

Following a retirement, the Participant shall remain eligible to receive Shares in respect of Restricted Stock Units scheduled to vest on the first scheduled Vesting Date occurring after the effective date of retirement. Restricted Stock Units with a subsequent Vesting Date shall be immediately cancelled, without prior notice or compensation.



In addition to the foregoing, the Board of Directors of the Company may waive the Continued Employment Condition in whole or in part on a case by case basis, in its discretion.

##### **5 Delivery and Custody of the Shares**

On the first Paris business day following each scheduled Vesting Date, the Company should deliver to each Participant the Shares underlying the Restricted Stock Units that will have vested on such Vesting Date, following compliance with the conditions and criteria of Vesting set forth in this Plan. The Company will ensure that the delivery will occur at the scheduled date, however a processing delay may apply during the delivery process which should not in any case hinder the rights of the Participant to receive Shares.

The Shares will be delivered in securities accounts under each Participant's name maintained by Banque Transatlantique or any other financial institution appointed by DBV for the administration of this Free Share Plan and will be held in administered registered form ("nominatif administré").

In addition, subject to applicable law and regulations, the Company may, prior to each Delivery, in the discretion of the Board, determine that the Shares may, or must, be held through a *fonds commun de placement d'entreprise* or "FCPE" or any other custodial arrangement.

As an exception to the foregoing, the Shares underlying the Restricted Stock Units that will have vested prior to the second anniversary of the Grant Date, will be delivered on the first [Paris] business day following the second anniversary and not before, except in case of death or disability.

Shares delivered on or after the second anniversary of the Grant Date will be freely transferable and not subject to any lock-up period.

In all cases, Shares received under this Plan may not, pursuant to the current provisions of Article L. 22-10-59 of the French Commercial Code, be transferred or sold:

- During the period of thirty calendar days that precede the date on which the annual, half-year or quarterly results of the Company are published, and
- By the members of the Board of directors, the Chief Executive Officer or Deputy Executive Officers, if any, and by any employee aware of insider information, within the meaning of Article 7 of regulation (EU) n° 596/2014 of the European Parliament and of the Council of 16 April 2014 on Market Abuse, which has not been made public.

Should periods defined under Article L. 22-10-59 of the French Commercial Code change over time, or be deleted, any new provision will automatically replace the provisions described above.

More generally, Participants will be required to adhere to the Company's Insider Trading Policy and to applicable French and U.S. federal and state laws.



Notwithstanding anything in this Plan to the contrary, the delivery of any Shares shall be conditioned on compliance with all applicable laws and regulations. The Company shall not be required to deliver Shares in any circumstances that it deems not to be in compliance with such laws and regulations.

If any such law or regulation shall require the Company, or any Participant to take any action in connection with delivery, the delivery of Shares shall be suspended and deferred until such action shall have been taken.

#### **6 Characteristics of the Shares**

The Shares delivered to the Participants will be new or existing ordinary shares, at the choice of the Board of Directors. In the absence of a choice before the delivery date, then the Shares will be new shares.

The new Shares issued in favor of some or all the Participants shall have the same rights as those attached to the existing DBV Technologies shares as from their issuance.

#### **7 Adjustment of the number of Shares**

During the Vesting Period, in the event of a redemption or reduction of share capital, a change in the allocation of profits, a grant of free shares to all of the shareholders, an increase in share capital by incorporation of reserves, profits or share premium, a distribution of reserves, a share buy-back at a price above the share price on the stock exchange or any issue of equity instruments that includes subscription rights reserved for the shareholders, the maximum number of Shares awarded pursuant to the Plan may be adjusted by the Board of Directors of the Company in order to take into account such transaction, in a similar manner to the adjustment modalities provided by French law governing options to subscribe or acquire shares. The same applies in case of stock-split or reverse stock-split with respect to the Shares.

If such a situation is not covered by existing French law governing options to subscribe or acquire shares, the General Meeting of Shareholders or the Board of Directors when deciding to proceed with such securities issuance or other modification of the share capital may adopt any adjustment measures necessary to protect the rights of the Participants, using by analogy French law governing similar cases.

Each Participant will be informed of the practical terms of such an adjustment and of its consequences on his/her award of Restricted Stock Units.

In accordance with the 25th resolution of the Combined General Meeting dated May 12, 2022, the Restricted Stock Units which would have been freely awarded pursuant to such an adjustment will be deemed to have been awarded on the same day as the Restricted Stock Units initially awarded on the Grant Date.

#### **8 Restructuring and mergers**

In accordance with Article L. 225-197-1 III of the French Commercial Code, in case of a cashless share exchange (*échange sans souche*) as a result of a merger or a split (*scission*) achieved in accordance with applicable law during the Vesting Period, all the conditions provided in this Plan at the exchange date and, in particular, any Vesting conditions and remaining Vesting Period, will remain applicable to the Restricted Stock Units and to the Shares received in exchange.



#### **9 Tax and social treatment**

The Participant is responsible for making declarations and payments to be made or owed by him/her under applicable law and particularly with respect to his/her tax liabilities. Applicable social security law and tax law vary depending on the country of residence and/or of taxation of the Participants.

Each Participant is responsible for inquiring about the social and tax treatment applicable to him/her in any jurisdiction due to the award of Restricted Stock Units, the Vesting or the delivery of Shares, or at the time of the transfer of the Shares or upon payment of any dividend.

In the event that, as a consequence of the award of Restricted Stock Units, the Vesting or the delivery of Shares, DBV Technologies or a Group Company would have to pay taxes, social security contributions or any other taxes or governmental contribution on behalf of a Participant, DBV Technologies reserves the right to defer or prevent the delivery of the Shares until such time as the Participant has paid the corresponding amount to DBV Technologies or the relevant Group Company. DBV Technologies or, if applicable, the relevant Group Company has the right (i) to deduct the amount of these taxes, social security contributions, taxes or governmental contribution from the salary or other amount owed to the Participant, or (ii) to transfer or sell all or part of the Shares in order to fulfil the Participant's obligations, the proceeds being directly paid to DBV Technologies or the relevant Group Company.

Participants who have been employed in France during the Vesting Period but who would no longer be tax residents of France at the time of the transfer of the Shares will be subject to a withholding tax in France upon sale of the Shares. The tax will be deducted by the bank administering the Plan and may be withheld from the proceeds of such sale. The balance of the proceeds of the sale will only be credited to the personal account of the Participant after payment of any such tax due.

#### **10 Limitation of rights**

The Restricted Stock Units are not transferrable.

During the Vesting Period, the Participants are not the owners of the Shares which are not vested and do not have any right attached to such Shares, including voting rights or rights to dividends. They shall become full owners of the Shares and attached rights only upon delivery.

The Restricted Stock Units are separate from the Participant's employment contract and are not part of it. They are not taken into account to compute termination payments, pensions or any other payments made in the context of employment relationship termination.

None of the provisions which are set out in the Plan constitute an element of the employment contract of a Participant. The rights and obligations deriving from the employment relationship between the Participant and DBV Technologies or a Group Company shall in no way be affected by the Plan from which they are completely distinct. Participation in the Plan shall not confer any right relating to the continuation or creation of any employment relationship or any right upon termination of any such relationship.



#### **11 Interpretation of the Plan and Governing Law**

It will be the responsibility of the Board of Directors to construe the provisions of the Plan, if required, which may delegate this power to the Chief Executive Officer or to the Global Head of Human Resources of the Group.

This Plan is governed and shall be construed in accordance with French law and any claim relating thereto will be subject to the jurisdiction of the courts within the jurisdiction of the Court of Appeal of Paris. For Participants who are employed by a U.S. Company of the DBV Technologies Group, this Plan shall be construed in accordance with Section 409A of the United States Internal Revenue Code.

#### **12 Amendment of the Plan**

The terms of this Plan may be amended or supplemented by the Board of Directors (i) if it deems such amendment or supplement to be appropriate and not materially adverse to the interest of the affected Participants or (ii) by mutual agreement with the affected Participants.

More generally, in the event of a change in any legal, regulatory or accounting requirements applicable to the Plan, or any change in the interpretation thereof, in particular with respect to the fiscal or social treatment of any rights, payments or shares granted under the Plan, affecting the Company, any Group Company or any Participants, the terms of the Plan may be amended or supplemented by the Board of Directors, in its discretion and in the manner that it deems appropriate, in response to such change. For example, the Board of Directors may choose to shorten or lengthen the Vesting Period and/or to introduce a mandatory lock-up period and/or waive or modify any condition to Vesting and/or introduce new conditions. Furthermore, the Board of Directors may, if it deems the delivery of shares to any Participant would be impossible or inopportune, choose to pay instead an amount in cash of equivalent value, net of taxes and social charges. The amount and timing of any such payment would be determined by the Board of Directors in its discretion, by reference to the number and timing of any Shares to be otherwise delivered hereunder, to be valued by the Board of Directors on or around the scheduled delivery date, or by reference to an average price over a period preceding such date.

Participants shall not be entitled to any indemnification for any loss of value and/or increased tax or social costs resulting from any such amendments or supplements to the Plan, irrespective of whether such loss or increase is of general application or is specific to them in view of their personal situation.

\* \*

8/10

Annex 1

**Information Notice on the Protection of Personal Data**

By participating in the Plan, the Participant acknowledges that his/her personal information be subject to electronic data processing carried out under the control of the Company, with the assistance of his/her employer, in accordance with French Law n°78-17 of January 6, 1978 on data processing, data files and individual liberties, the EU Regulation on Data protection (2016/679) of April 27, 2016 (GDPR) and applicable local laws. It shall be implemented on the basis of legitimate interest (Article 6(1)(f) of the GDPR) because it is necessary for the administration of his/her rights under the plan and on for compliance of legal obligations (Article 6(1)(c) of the GDPR), for all purposes relating to the implementation of the Plan, *i.e.*:

- (i) administering and maintaining Participant records;
- (ii) providing information to members of the Group, registrars, brokers or third-party administrators of the Plan;
- (iii) providing information to future purchasers of the Company or of the business in which the Participant works;
- (iv) transferring information about the Participant to France or to another country or territory outside of his/her home country and/or of the European Economic Area that may not provide the same statutory protection for the information as the Participant's home country; and
- (v) complying with legal obligations.

All personal information subject to the electronic data processing is mandatory for the participation to the Plan. All this information will be transmitted (and be transferred to France) to and used for account administration and electronic storage of this data, by the internal departments of the Group in charge of the management of his/her shareholder's account, and to external entities designated to manage the same, and to all persons statutorily or expressly authorized by DBV Technologies or by an employer to hold and process this information (in particular the holder of shareholders accounts), as well as to any future acquirer of DBV Technologies or his/her employing company or the business in which he/she is working within the duration of the Plan. This personal information shall be retained for the time required for the completion of the Plan and for the purposes of the management of the shareholder's account, until he/she sells all his/her DBV Technologies shares under the Plan, and thereafter for archiving purposes until the expiration of the limitation period of any possible litigation relating to the processing of such data.



Every Participant will be able to exercise a right to access, to modify and to rectify, and as well as to delete (once he/she no longer holds any Shares under the Plan) any information relating to him/her. Furthermore, each Participant will have the right to restriction of processing and to object to processing as well as the right to data portability. The right of data portability shall allow the Participant to recover his/her data directly or to transfer them or have them transferred to another data controller (subject to legal limits). According to French law, he/she will have a right to define the directives in relation to the registration, the removal and the communication of his/her personal data after his/her death.

In some countries, local regulations require the express consent of the Participant for the processing and transfer of his/her personal data. In such a case, the Participant's consents, under the acceptance procedure, to the collection, use, storage and transfer of his/her personal data, within the framework of local law. Furthermore, local law may provide that he/she has the right to withdraw his/her consent for the processing of his/her personal data. However, his/her personal data is necessary for the processing of his/her participation to the Plan, the holding of his/her Shares under the Plan and the execution of all operations related to his/her investment. Accordingly, he/she will be able to exercise his/her right to withdraw his/her consent only when all the Shares held under the Plan have been sold.

The Company has appointed a data protection officer, who is responsible for compliance with this notice and can be contacted at the following address: [dataprivity@dbv-technologies.com](mailto:dataprivity@dbv-technologies.com).

The Participant have the right to lodge a complaint with his/her supervisory authority (in France, the supervisory authority is the CNIL), concerning the protection of personal data.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement No. 333-257569 on Form S-3, the Registration Statement No. 333-266449 on Form S-3, the Registration Statement No. 333-266448 on Form S-3, and the Registration Statement No. 333-199513 on Form S-8 of our report dated March 2, 2023, relating to the consolidated financial statements of DBV Technologies S.A. and subsidiaries (the "Company") as of and for the year ended December 31, 2022, appearing in this Annual Report on Form 10-K of the Company.

/s/ Deloitte & Associés

Paris-La Défense, France  
March 2, 2023

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements Nos. 333-257569, 333-266448 and 333-266449 on Form S-3 and the registration statement No. 333-199513 on Form S-8 of our report dated March 2, 2023, with respect to the consolidated financial statements of DBV Technologies S.A. and subsidiaries.

KPMG S.A.

*/s/* Cédric Adens  
Partner

Paris La Défense, France  
March 2, 2023

**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**

I, Daniel Tassé, certify that:

1. I have reviewed this Annual Report on Form 10-K of DBV Technologies S.A.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 2, 2023

*/s/* Daniel Tassé

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

**Certification by 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**

I, Sébastien Robitaille, certify that:

1. I have reviewed this Annual Report on Form 10-K of DBV Technologies S.A.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 2, 2023

/s/ Sébastien Robitaille

Name: Sébastien Robitaille  
Title: Chief Financial Officer  
(*Principal Financial Officer*)

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Daniel Tassé, Chief Executive Officer of DBV Technologies S.A. (the "Company"), and Sébastien Robitaille, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 2, 2023

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 2<sup>nd</sup> day of March, 2023.

/s/ Daniel Tassé

Daniel Tassé  
Chief Executive Officer

/s/ Sébastien Robitaille

Sébastien Robitaille  
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of DBV Technologies S.A. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.