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DELTA REPORT

10-K

DBVT - DBV TECHNOLOGIES S.A.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	6316
CHANGES	255
DELETIONS	2046
ADDITIONS	4015

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORMFORM 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 December 31, 2023

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 number001-36697

DBV TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

France	**Not applicable**
State or other jurisdiction of incorporation or organization	**(I.R.S. Employer Identification No.)**
177-181avenue Pierre Brossolette Montrouge 92120 France	
Montrouge 92120 France	
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representingone-halfof 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 Depositary Shares.

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of RegulationS-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, anon-acceleratedfiler, 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 Rule12b-2of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2of the Act). ☐ Yes ☒ No

The aggregate market value of the voting andnon-votingcommon equity held bynon-affiliatesbased on the closing price per American Depositary Share, or ADS, of the registrant's ADSs on The Nasdaq Global Select Market on June 30, 2022 June 30, 2023 (the last business day of the registrant's most recently completed second fiscal quarter) was $324.02
$183.24 million.

As of December 31, 2022 December 31, 2023, the registrant h ad 94,137,145 had 96,431,770 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 2024 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 December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form10-K.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS.

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

- 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;
    - 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 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;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- If we do not secure collaborations with strategic partners to test, commercialize and manufacture certain product candidates 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 self- regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could negatively affect our operating results and business.

- Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our results of operations.

- We may be forced to repay conditional advances prematurely if we fail to comply with our contractual obligations under the applicable innovation grant agreements.

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

- If we are not able to comply with the applicable continued listing requirements or standards of the Nasdaq 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.

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Unless the context otherwise requires, we use the terms "DBV," "DBV Technologies," the "Company," "we," "us" and "our" in this Annual Report on Form 10-K, or Annual Report, to refer to DBV Technologies S.A. and, where appropriate, its consolidated subsidiaries. "Viaskin™ "Viaskin™", "EPIT™ "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. **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™, 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 eleven clinical trials, including four Phase 2 trials and three four completed Phase 3 trials. We also have an ongoing Phase 3 trial of Viaskin Peanut in children ages four to seven with peanut allergy. allergy, as well as two planned Phase 3 supplementary safety studies, one in peanut-allergic children ages four through seven, and one in peanut-allergic toddlers, ages one through three.

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 UnionUnion.**
- **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.

1

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

1

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 in peanut-allergic individuals and their caregivers. The current management of peanut allergy has significant limitations and highlights the need for safe and effective treatments that can induce clinical desensitization (i.e., increased tolerance to peanut allergen), thus minimizing the risk of reaction due to accidental ingestion.

Current and Emerging Peanut Allergy Treatments

Several non-specific and allergen-specific treatment approaches are in various stages of clinical development for the treatment of peanut allergy. Food allergen-specific approaches include 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. Xolair® (omalizumab), an anti-immunoglobulin E (IgE) antibody was recently approved by the FDA for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. SLIT for peanut allergy has demonstrated evidence of clinical success, with a more satisfactory side effect profile compared to OIT. Despite the

evident interest of clinicians to further evaluate these treatment procedures, OIT and SLIT may not be applicable across all ages and risk categories of peanut-allergic children and adults.

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 antigen, such as food protein. This

technology platform, which we call Viaskin, is an innovative approach to potentially treating immunological disorders, with a primary focus on food allergy. In EPIT, intact skin is exposed to allergen via the Viaskin technology using a patch that contains microgram amounts of food protein. Allergen applied via EPIT is captured in the superficial layers of the skin by Langerhans specialized antigen presenting cells (Langerhans cells within the epidermis), as well as dermal dendritic cells, thus limiting exposure to the bloodstream. In experimental models, EPIT induced a population of regulatory T cells, or Tregs, with specific properties that resulted in suppression of allergic

allergic. symptoms and protection against further sensitizations. EPIT-induced epigenetic modifications favored a Treg- mediated 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 capture the protein at the surface of the skin, process it and present its epitopes to the lymphocytes T-lymphocytes in the lymph nodes.

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

Our Product Candidates

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

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 of the following clinical trials:

- *PEPITES (Peanut EPIT Efficacy and Safety Study)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 (PEPOPITen ES OPen Label ExtE extension Study) nsion 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 up to four additional years, while patients who received placebo during PEPITES were treated with Viaskin Peanut 250 µg for three up to five 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.

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 the original patch (which we call 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

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 (cVP), 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 (in terms of the surface area in contact with the skin) relative to the current patch cVP 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) PREQUAL (a Phase 1 study in healthy volunteers to optimize allergen sample collection methodologies and validate the assays DBV intended to be used in EQUAL, a second Phase 1 study that was planned (but not initiated) comparing allergen uptake following application of mVP and cVP), 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(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 "Abylqis®", 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 reviews the application and provide provides 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 "Abylqis", 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.

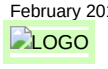
PEPITES (Pe Peaanut nut EPIT Ef Efficacy icacy and Sa Safety ety Study)

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.

The primary responder analysis was conducted after 12 months of treatment. For patients with a baseline peanut protein ED equal to or less than 10 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For patients with a baseline ED greater than
10 mg but less than or equal to 300 mg, a responder was defined as a patient with a peanut protein ED equal to or greater than 1,000 mg of peanut protein after 12 months of treatment. Secondary endpoints included the change from baseline of mean and median cumulative reactive dose 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. The clinical relevance of this is not known. Detailed results were published in The Journal of the American Medical Association (JAMA) in February 2019.



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 or placebo reached a mean CRD of
906 mg (median 444 mg) and 361 mg (median 144 mg) of peanut protein, respectively. Patients in the active and placebo arms entered the trial at similar sensitivity levels; mean CRD at baseline was 211.7 mg (median 144 mg) in the Viaskin Peanut arm and 212.5 mg (median 144 mg) in the placebo arm. A difference in the CRD was observed between Viaskin Peanut and placebo (nominal p-value < 0.001) following 12 months of treatment.

Exploratory analyses showed that changes in peanut-specific biomarkers, including immunoglobulin E, orIgE, E(IgE), and immunoglobulin G4, orIgG4, G4(IgG4), support the immunomodulatory effect with of Viaskin Peanut. The median observed increase from baseline in peanut-specific IgE was greater in the Viaskin Peanut group vs placebo group, respectively, at month 3 (70.1 kilounits of antibody per liter, or kUA/L vs. 9.8 kUA/L) and month 6 (27.4 kUA/L vs. 1.32 kUA/L). However, at month 12, peanut-specific IgE levels were observed to return to near baseline in both groups (1.1 kUA/L vs. -1.1 kUA/L). Median peanut-specific IgG4 were observed to increase over time in
the Viaskin Peanut group (change from baseline at month 3: 0.81 mg/L; month 6: 1.79 mg/L; month 12: 3.27 mg/L), while levels remained unchanged from baseline in the placebo group. The change from baseline in
peanut-specific IgG4 was greater at all time points with Viaskin Peanut vs placebo, and the groups were observed to be highly distinguished by this marker, given a flat trend in the placebo arm. These changes are consistent with trends that have been observed with other forms of immunotherapy such as for venom and inhalant allergies.

PEPITES Immunological Responses

In a post-hoc analysis, the majority of patients subjects on Viaskin Peanut exhibited an increased ED compared to the placebo group (62.6% in active vs. 28% in placebo) at 12 months. An additional post-hoc analysis showed that 53.1% of patients subjects treated with Viaskin Peanut increased their baseline ED from 100 mg or less to 300 mg or

more, compared to 19% in the placebo group. Based on this analysis, we believe that increasing the ED should translate to a reduction in the risk of reaction to accidental peanut exposures, as it will take a higher ingestion quantity to trigger a reaction. Indeed, based on quantitative risk analysis, 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 subjects 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

patients subjects (3.4%) of possibly or probably treatment-related anaphylaxis occurred, and all were classified as mild or moderate without evidence of cardiovascular, neurologic, or respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight patients subjects continued on Viaskin Peanut in the trial.

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

PEOPLE (PE PEPPITES ITES Ope Open Labn el La Extbel ension Ex Stutension Study) dy)

The PEOPLE trial, which was 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. The last patient visit of the PEOPLE trial occurred on October 12, 2022.

In January 2020, we announced positive topline results of up to Year 3 from 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 Results of the PEOPLE trial which completed for participants receiving 3 years of active treatment were published in the Journal of Allergy and Clinical Immunology in October 2022, is an open-label extension study that evaluated 2020.

Of the long-term safety, tolerability and efficacy of Viaskin Peanut 250 µg 356 participants who were enrolled in patients who have completed the Phase 3 PEPITES, trial. 298 eligible participants opted to enroll in PEOPLE. Of the 213 patients who were randomized in the active treatment arm of PEPITES and completed the 12-month trial, 198 patients opted to enter the PEOPLE clinical trial (safety population). Of these patients, 148 were considered completers after 36 months and 141 patients subjects 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 subjects(per protocol).

Topline results from Year 3 of PEOPLE support the long-term tolerability and clinical benefit of Viaskin Peanut, demonstrating desensitization over 36 months of treatment, with 75.9% (107/141) of patients increasing their ED from baseline. After 36 months, 51.8% (73/141) of patients subjects reached an ED of at least 1,000 mg peanut protein, an increase of 40.4% (57/141) relative to Month 12. In addition, 13.5% (19/141) of patients subjects 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.

Changes in ED were maintained or improved over 3 years in the majority of subjects in the Open-label extension study (Fleischer DM, et al. *J Allergy Clin Immunol.* 2020;146:863-874).

The safety profile of Viaskin Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. study participants aged 4-11 years old. During the PEOPLE trial, the most common adverse events were mild to moderate skin reactions localized to the administration site, and there was no epinephrine use deemed related to treatment. No treatment related serious adverse events were reported. One patient subject experienced one case of mild anaphylaxis that was

determined by the investigator to be possibly related to treatment and resolved without treatment. Treatment compliance remained high throughout the trial at a mean of 98% over three years of treatment. Low discontinuations due to adverse events were observed, with two children discontinuing the trial due to treatment- related TEAEs during PEOPLE.

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

REALISE (REAL Life Use and Safety of EPIT)

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

No DBPCFCs were required for entry or during the trial, in order to replicate routine clinical practice. Patients Subjects in the clinical trial were selected, as per clinical practice, based on a well-documented medical history of IgE-mediatedIgE- 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 was 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 wheal. Exploratory criteria also included scores from patients' subjects' 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 subjects in 32 centers across North America.

After the initial blinded six-month period, 97.5% of patients subjects in both the placebo and active arms opted into an open-label portion of the study, which continued monitoring patients subjects 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 µg. The most commonly reported adverse events were local application site reactions, which were mostly mild and moderate in nature. No imbalance in SAEs was observed in the trial, with three cases in three patients in the active arm (1.0%) and two cases in two patients subjects in the placebo arm (2.0%). One case in one patient subject in the active arm was qualified by the investigator as moderate anaphylaxis probably related to treatment. The patient subject responded to standard outpatient therapy. In the six-month blinded period, the discontinuation rate was 2.5%, with a 1.0% dropout related to adverse events. The mean patient participant compliance was above 95%.

In November 2021, long-term results of from REALISE, including the safety of Viaskin Peanut over three years and potential impact on health-related quality of life (HRQL), were presented at the 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. age, given the high unmet need and absence of approved treatments for this population. This program is independent from the Viaskin Peanut Program in 4–7-year-olds and uses the cVP (original patch).

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

- EPITOPE *(EPIT in Toddlers with Peanut Allergy)*, a randomized, two-part, pivotal Phase 3 clinical trial assessing the safety and efficacy of Viaskin Peanut for the treatment of peanut-allergic toddlers one to three years of age.
- COMFORT Toddlers (*Characterization of the Optimal Management of Food allergy Relief and Treatment), a supplemental safety study to bring the (total) number of subjects on active therapy close to 600 in total when combined with EPITOPE.*
- EPOPEX (*Phase 3 Open-Label Extension to the EPITOPE Trial), a follow-up of the EPITOPE study to evaluate the long-term efficacy and safety of Viaskin Peanut in very young children,*

In August 2017, we initiated Part A of the EPITOPE (EPIT in Toddlers with Peanut Allergy) trial of Viaskin

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 subject was enrolled in Part B of EPITOPE.

On June 26, 2020, we announced that in Part A, patients subjects 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 that was studied in Part B of the study. Enrollment of Part B of EPITOPE was complete completed in the 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 (DBPCFC) was administered at baseline and month 12 to determine a subject's ED at each timepoint. A treatment responder was defined as either a subject with a baseline ED ≤10 mg who reached an ED ≥300 mg of peanut protein at month 12, or a subject with a baseline ED >10 mg and ≤300 mg who reached an ED ≥1,000 mg of peanut protein at month 12.

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

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

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

Overall, 21 subjects (8.6%) in the Viaskin Peanut arm and 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.

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 In May 2023, the EPITOPE trial results were published in the New England Journal of Medicine with an accompanying editorial article from Alkis Togias titled "Good News for Toddlers with Peanut Allergies." The EPITOPE primary data were also presented as an oral presentation at future medical congresses as well as submit them for publication the American College of

Allergy, Asthma and Immunology (ACAAI) in a peer-reviewed journal. In addition, we intend November 2022 . We anticipate to further analyze perform additional analyses of the data collected from EPITOPE for further potential publication opportunities.

Supplemental Safety Study in Toddlers (COMFORT Toddlers)

In April 2023, we received pre-BLA Type B Meeting Written Responses from the FDA related to the Viaskin Peanut program in toddlers. The FDA did not request an additional efficacy study in 1-3-year-olds (i.e., the Agency agreed that the primary endpoint was satisfactorily met in DBV's Phase 3 trial EPITOPE). There was

agreement with the FDA to conduct a supplemental safety study (COMFORT Toddlers) using the original square (cVP) Viaskin™ Peanut patch to augment the safety data collected from EPITOPE and explore regulatory pathways have close to 600 total subjects on active treatment in the controlled safety database.

In July 2023, we received Type C Meeting Written Responses from the FDA regarding key study design elements for the COMFORT Toddlers supplemental safety study. In summary, COMFORT Toddlers will be a 6-month Double-Blind, Placebo-Controlled (DBPC) study involving approximately 400 toddlers, aged 1 through 3 years, randomized at a 3:1 ratio (active to placebo) with a 12-month open-label extension. Subsequently, in October 2023, we received feedback from the FDA addressing the remaining protocol design elements for COMFORT Toddlers. This feedback included language simplification for how the product should be used (i.e., where each epicutaneous system is intended to be worn for a full day (24 hours)). Furthermore, the key inclusion criteria for the COMFORT Toddlers study will be based on a Double-Blind, Placebo-Controlled Food Challenge (DBPCFC) performed at entry. Recruiting a study population close to EPITOPE is critical for the future BLA and aligning with the intended patient population if Viaskin Peanut is approved. We believe that an entry DBPCFC represents the best way to ensure that the optimal study population (i.e., as close to EPITOPE as possible) is enrolled. The revised protocol design of the safety study was submitted to the FDA in children ages 1 Q4 2023.

Interim Results from Open-label Extension to 3 years, given EPITOPE Study (EPOPEX)

Following the high unmet need and absence 12-month treatment period of approved treatments for this vulnerable population.

We initiated EPITOPE, eligible subjects could opt to enroll in the EPOPEX trial, which is an ongoing open-label, extension ("OLE") study for up to three years of active total treatment. This ongoing, open label extension to EPITOPE is known as EPOPEX and is evaluating the long-term clinical benefit and safety of Viaskin Peanut 250 mg in subjects who have completed the Phase III 3 EPITOPE trial. Subjects randomized to active treatment in EPITOPE could receive an additional 2-years of treatment in the OLE and subjects randomized to placebo in EPITOPE cross-over to receive 3 years of active treatment with annual double-blind placebo-controlled food challenges (DBPCFC) and safety assessments.

266 eligible EPITOPE participants enrolled in EPOPEX; 244 underwent the Month-24 DBPCFC (n=166 subjects treated with Viaskin Peanut 250 µg for 24 months); 78 subjects originally randomized to the placebo arm of EPITOPE who crossed-over and received active treatment with Viaskin Peanut for 1 year in the OLE. In November 2023, we announced the interim analyses from the first year of the open-label extension of EPITOPE. These data were presented at the annual American College of Allergy, Asthma, and Immunology (ACAAI) in November 2023. Using the same primary endpoint definition that was used in EPITOPE, 83.9% of subjects who completed the DBPCFC met the responder criteria after 24 months. This compares to 67% of subjects after one year of therapy. 81.3% of Viaskin Peanut subjects reached an eliciting dose (ED) of ≥1000 mg (equivalent to

approximately 3 peanuts; central chart), relative to 64% after 1-year of treatment observed in EPITOPE. Furthermore, following an additional year of treatment, 55.9% completed the food challenge without meeting the stopping criteria (i.e., consumed the equivalent of about 12-14 peanuts).

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

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

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

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

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

In placebo-treated EPITOPE participants, outcomes after 12 months of cross-over to Viaskin Peanut in EPOPEX were consistent with EPITOPE treatment results: 68.0% were responders (compared to 67% of subjects on active treatment in the first year of EPITOPE); 62.7% of subjects reached an ED ≥1000 mg (relative to 64.2% in EPITOPE); 36.5% reached an ED ≥2000 mg (relative to 37% in EPITOPE); 28.4% completed the DBPCFC without meeting stopping criteria (relative to 30.7% in EPITOPE). There was 1 event of treatment-related anaphylaxis in Year 2.

We anticipate communicating the results of the Year Two results as a manuscript that is currently in preparation. In addition, We anticipate that Month 36 results will become available in the second half of 2024 and we anticipate additional analyses of that data will be performed.

Viaskin Peanut for Children ages 4-7

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

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

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

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.

On March 7, 2023, the Company announced screening of the first subject in VITESSE. Screening of the last subject was anticipated in the first half of 2024, and topline results are anticipated in the first half of 2025.

We expect to enroll 600 subjects for participation in the VITESSE study, randomized 2:1 active to placebo. The primary efficacy endpoint is the percentage of treatment responders in the active versus placebo arms at month 12. The primary efficacy analysis includes the success criterion of the lower bound of the confidence interval of the difference in responder rates between active and placebo groups being greater than or equal to 15%.

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

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

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

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

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

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We expect to initiate patient initiated subject screening for VITESSE in Q1 2023 with (the first subject was screened in February 2023 and randomized in March) and anticipate that the last patient will be screened in 1H 2024 and topline results are anticipated in 1H 2025. by Q3 2024.

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

We In 2024, we plan to initiate a separate supplemental safety study (COMFORT Children) in approximately 275 additional subjects, peanut-allergic children aged 4-7 years. COMFORT Children comprises a 6-month, randomized, 3:1 double-blind, placebo-controlled period followed by a 12-month, open-label, single-arm active versus placebo. treatment period. The additional safety data generated by this six-month the 6-month DBPC study will supplement the safety data generated by the VITESSE trial, resulting in a controlled safety database comprised of approximately close to 600 children ages (total) aged 4 to 7 years treated with Viaskin Peanut.

In July 2023, we received Type C Meeting Written Responses from the FDA regarding key study design elements for COMFORT Children. In summary, there was an agreement with the Agency that COMFORT Children will be a Double-Blind, Placebo-Controlled study involving approximately 270 children, randomized at a 3:1 ratio (active to placebo). Participation will not necessitate a food challenge, and patch adhesion data will be generated using the same approach as previously agreed upon with the FDA for the VITESSE phase 3 study.

Subsequently, in October 2023, we received feedback from the FDA addressing the remaining protocol design elements for COMFORT Children. This feedback included language simplification for how Viaskin should be used. Furthermore, the key inclusion criteria for the COMFORT Children study will be based on a physician-diagnosed peanut allergy, peanut-specific IgE and a Skin Prick Test (with no requirement for a DBPCFC). The revised protocol design of the safety study will be was submitted to the FDA and in Q4 2023. COMFORT Children is expected anticipated to be similar to initiated towards the REALISE (REAL Life Use and Safety end of EPIT) VITESSE enrollment. We intend that enrollment of the COMFORT Children safety study that we previously conducted will be strategically timed to avoid competition with Viaskin Peanut in children ages 4 to 11 years. the VITESSE study for the same subjects.

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

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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 subjects 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,(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 (RSV), as well as potential treatments for Crohn's inflammatory bowel disease (IBD), celiac disease and type I 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 entered into a Development Collaboration and License Agreement (the "Collaboration Agreement") with Société des Produits Nestlé S.A. (formerly NESTEC S.A.) ("NESTEC"). The Collaboration Agreement related to an exclusive global collaboration with Nestlé Health Science to develop for the development and, if approved, commercialization of MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of CMPA (non-mediated(non-mediated IgE) in infants and children under 2 years old. infants.

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

On October 30, 2023, the Company and NESTEC entered into a Phase 2 clinical trial of MAG1C. Mutual Termination Letter Agreement terminating the Collaboration Agreement. Each party remains responsible for its own costs and expenses related to its respective wind-down activities. Any and all licenses and sublicenses, granted by either party to the other party under the Collaboration Agreement, including, without limitation, any licenses to intellectual property, were revoked and terminated.

We may explore selective collaborations with parties who have relevant clinical and commercial expertise in other geographies, including certain European countries, and indications outside of food allergies.

Potential Biomarker Applications

We are continuing to explore other cellular mechanisms modulated by EPIT™, EPIT, such as biomarkers, in collaboration with Mount Sinai Hospital external companies and academic institutions in both the United States and Commissariat à l'Énergie Atomique et aux Énergies Alternatives, or CEA, in France. EU. 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 planned 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 into 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 in any jurisdiction 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.

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. We also have extensive know-how and trade secrets covering part of the Viaskin patch manufacturing method using electrospray technology.

These patents and applications generally fall into four five broad categories:

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

- patents and patent applications which we own relating to our electrospray method of manufacturing the Viaskin electrostatic patch, which may expire as early as 2029;
- patents and patent applications we co-own with Assistance-Publique-Hôpitaux de Paris, or 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;
- design patents and patent applications, which we own relating to various components of the Viaskin patch, which may expire as early as 2028; 2038; 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.
- 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 Extension and Marketing Exclusivity

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

The amount of time by which a patent term restoration period may be extended is generally one-half the time between the effective date of an IND submission and the submission date of a BLA plus the time between the submission date of a BLA and the FDA's approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. patent, and within 60 days of the FDA's approval of the product. The U.S. PTO, Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. extension. In the future, we may apply for restoration extension 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

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

Absent early termination, the assignment, development and co-ownership agreement will automatically terminate upon the expiration 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 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; oral mucosal, or OMIT; and cutaneuos or intranasal immunotherapy, synthetic, or denatured allergens, medicinal herbs, small molecule inhibitors, or combinations of medicines or methods.

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

There is one treatment for peanut allergy 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 2020 and divested the Palforzia business to function as a stand- alone business unit Stallergenes Greer in September 2023. In addition, Xolair (omalizumab) is approved by the FDA for the reduction of allergic reactions including reducing the risk of anaphylaxis, that will manage may occur with accidental exposure to one or more food allergens, including peanut. Omalizumab is an anti-immunoglobulin E (IgE) monoclonal antibody that is administered via subcutaneous injection. The prescribing information for both Palforzia and Xolair indicate patients should continue to avoid all of Nestlé's global pharmaceutical business. foods to which they are allergic.

Government Regulation

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

U.S. Biological Product Development

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

Our product candidates must be approved by the FDA through the 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;
    - 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;
    - 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
    - potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the pre-clinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the pre-clinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization

from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or regulatory non-compliance. Accordingly, we cannot be sure that submission of an 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.

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

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

Progress reports detailing the results of the a clinical trials trial must be submitted at least annually periodically to the FDA and written FDA. Written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or

terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug product has been associated with unexpected serious harm to subjects or patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides

authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We A sponsor 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 of a clinical trial, data generated from such trial is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product candidate and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the a biologic product for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials and positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic product may be marketed in the United States.

Under the Prescription Drug User Fee Act, 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 may be 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 such BLA within ten months of the filing date for standard review or six months of the filing date for priority review (if granted by the FDA), if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. 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 the sponsor during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we the sponsor may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product candidate to determine whether they comply with cGMPs. The FDA will not approve the product candidate unless it determines that the manufacturing

processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product candidate within required specifications. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes 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 a sponsor interprets the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and we a sponsor may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, 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 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

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. biologic product. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That

determination is based on the “primary mode of action” of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product.

Expedited Development and Review Programs

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

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

Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint
other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a

drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. If the FDA concludes that a drug shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions as it deems necessary to assure safe use of the drug, such as:

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

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

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 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

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 or the EU, 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 EU are subject to significant regulatory controls. Certain preclinical (also termed "non-clinical""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(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

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

The CTR 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 European Medicines Agency, or 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 CTR includes a reasoned proposed deferral three-year transition 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. varies. For clinical trials in relation to which an application for authorization approval was made on the basis of the CTD before January 31, 2022 January 31, 2023, 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 related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework. framework before January 31, 2025.

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 advanced therapy medicinal products, or 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 EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

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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.

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 Decentralised 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

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 fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

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

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, 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 the MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until

there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and

study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, 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 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 The EU regulates medical devices and medicinal products separately, and through different legislative instruments. Products that are a combination of a medicinal product and a medical device are may be regulated as either a medicinal product, or a medical device or, subject to certain requirements, on the basis of both sets of rules. The applicable requirements governing placing a drug-device combination on the EU market will vary depending on the type of drug-device combination product and on which component of the components of the combination has the primary mode of action.

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

approach, the competent authorities responsible for medicinal products will review the specific aspects of the medical devices part of the product which are relevant to the safety and efficacy of the medicinal product and the Notified Body – where applicable – will evaluate the relevant GSPRs of the device.

Drug-device combination products that form a single integral product that is not reusable and for which the action of the medicinal products is ancillary to that of the medical device are governed by the regulatory framework applicable to MDR. However, the quality, safety and usefulness of the medicinal product must also be verified as part of the device and a scientific opinion from a national competent authority of an EU Member State or from the EMA, depending on its nature and therapeutic intention, must be sought regarding the quality and safety of the medicinal product, including the benefit or risk of its incorporation into the medical device. Where a medical device incorporates a the primary mode of action of the combined product comes from the medicinal product as an integral part as a single use drug delivery system, , it is regulated as a medicinal product. In this case, the medicinal product should also be compliant with regulation (EU) 2017/745 and particularly the article 117. This article requires a Notified Body opinion on the conformity of the device part to the relevant General Safety and Performance Requirements, or GSPRs of the MDR will apply to the safety and performance of the device element. MDR.

Other Regulatory Matters

Brexit UK Regulations

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning changed the future regulatory 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 regulator 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. and medical

Among the changes that will now occur,

devices. Great Britain (England, Scotland and Wales) will be treated as is now a third country. country to the EU. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. As part of rules for now.

The UK regulatory framework in relation to clinical trials is governed by the Agreement, Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU and CTD, as implemented into UK national law through secondary legislation. On January 17, 2022, the MHRA launched an eight-week consultation on reframing the UK will recognize GMP inspections carried out by legislation for clinical trials, and which aimed 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 UK Government published its response to the other party and the acceptance of official GMP documents issued by the other party. The Agreement also encourages, although consultation on March 21, 2023 confirming that it does not oblige, the parties to consult one another on proposals to introduce significant would bring forward changes to technical the legislation. These resulting legislative amendments will determine how closely the UK regulations or inspection procedures. Among will align with the areas of absence of mutual recognition are batch testing CTR. In October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and batch release. The UK has unilaterally agreed risk-proportionate approach to accept EU batch testing initial clinical trial applications for Phase 4 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 low-risk Phase 3 clinical trial applications.

Marketing authorizations 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 are governed by the marketing authorizations granted by the European Commission. Human Medicines Regulations (SI 2012/1916), as amended. Since January 1, 2021, an applicant for a the EU centralized procedure marketing authorization can no longer be established in the UK. Since As a result, since this date, companies established in the UK cannot use the EU centralized procedure and instead must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA marketing authorization to market products in the UK. Until December 31, 2023 All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorization, effective in Great Britain only, free of charge on January 1, 2021, MHRA may rely unless the marketing authorization holder opted-out of this possibility. Northern Ireland currently remains within the scope of EU authorizations in relation to centrally authorized medicinal products. Accordingly, until the Windsor Framework is implemented in Northern Ireland on a

decision taken by January 1, 2025, products falling within the European Commission on scope of the approval of a new EU centralized procedure marketing can only be authorized through UK national authorization when determining an application for a procedures in 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. Britain.

The MHRA has also established its own decentralized introduced changes to national marketing authorization procedures. This includes introduction of procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment route, a rolling review procedure and the International Recognition Procedures which entered into application on January 1, 2024. Since January 1, 2024, the MHRA may also rely on the International Recognition Procedure, or IRP, when reviewing certain types of marketing authorization applications. This procedure is available for applicants for marketing authorization who have already received an authorization for the same product from a reference regulator. These include the FDA, the EMA, and national competent authorities of individual EEA countries. A positive opinion from the EMA and CHMP, or a positive end of procedure outcome from the mutual recognition or decentralized procedures which enable marketing authorizations approved in EU Member States through decentralized and mutual recognition procedures are considered to be recognised in authorizations for the United Kingdom or Great Britain. Since Brexit, the MHRA has been updating various aspects purposes of the regulatory regime IRP.

There is no pre-marketing authorization orphan designation for medicinal products in the UK. These include: introducing Instead, the Innovative Licensing and Access Procedure to accelerate the time to market and

facilitate patient access MHRA reviews applications for innovative medicinal products; updates orphan designation in parallel to the UK national approval procedure, introducing a 150-day objective for assessing applications for corresponding marketing authorizations authorization application. The criteria are essentially the same as those in the UK, EU, but have been tailored for the market. This includes the criterion that prevalence of the condition in Great Britain, and Northern Ireland and rather than the EU, must not be more than five in 10,000. Upon the grant of a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission).

It is currently unclear with orphan status, the medicinal product will benefit from up to what extent the UK will seek to align its regulations with the EU 10 years of market exclusivity from similar products in the future. approved orphan indication. 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 start of this market exclusivity period will be set from the UK statute book by date of first approval of the end of 2023, may result product in a divergence of approach between the EU and the UK. Great Britain.

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 sponsors may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

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 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

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

$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, 2032,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, 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. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is

currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, In response to the Biden administration released an additional administration's October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three new models for lowering drug costs for Medicare testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it isuncertain if that will continue under the new framework. 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

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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.

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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 An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In France, for example, effective access to the market can be achieved either at a free price, decided by the pharmaceutical company, or with a system of cover/reimbursement with a price regulated by the authorities. In this case, the future products must be included, for coverage by hospitals, on the list of proprietary medicinal products approved for use by local authorities and various public services (known as the "*Liste Collectivités*") (Article L. 5123-2 of the Public Health Code) or included on the list of proprietary medicinal products reimbursable to insured persons (known as the "*Liste Sécurité Sociale*") for reimbursement by the Social Security system (Article L. 162-17 of the Social Security Code).

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 LEEM (the trade union representing the pharmaceutical industries) and CEPS. The last framework agreement was signed on March 5, 2021 and has a three-year term. In addition, the transfer prices of medicines on the Sus List and the Retrocession List are also set by agreement between the operating laboratory and the CEPS.

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

Other Healthcare Laws and Compliance Requirements

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or

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

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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;

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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 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;

- federal Health Insurance Portability and Accountability Act of 1996, or 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 anti-kickback and false claims laws which may apply to items or services reimbursed by any third- party 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 healthcare professionals are also governed by strict laws, such as national anti-bribery laws of EU Member States, national sunshine rules and regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in administrative penalties, fines or imprisonment, reputational risk and public reprimands.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and

abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or

restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to significant administrative, civil, and/or criminal sanctions, including individual imprisonment and exclusion from government funded healthcare programs.

Data Privacy and security 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 EU's General Data Protection Regulation ((EU) 2016/679), or GDPR, and the United Kingdom's UK'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. EU. The GDPR enhances data protection obligations for controllers and processors of personal data, including stringent requirements relating to the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for high-risk processing, limitations on retention of personal data and mandatory data breach notification and privacy by design requirements, and creates direct obligations on service providers acting as data processors. The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection, such as the U.S. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to 20 million Euros or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim compensation for damages resulting from infringement of the GDPR.

Following the United Kingdom's UK'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 and Human Capital Resources

As of December 31, 2022 December 31, 2023, we had 85 104 full-time employees, including approximately 20 23 with M.D. or Ph.D. degrees, and 1 part-time employee. Of Most 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. 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.

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 $72.7million and $97.8 million $96.3 million for the years ended December 31, 2022 December 31, 2023 and 2021 2022 respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $259.6 million. $238.9 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

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;
    - 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;
    - 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;
    - acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
    - 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 $141.4 million as of December 31, 2022 December 31, 2023 will be sufficient to fund our operations until December 31, 2024.

The company has incurred operating losses and negative cash flows from operations since inception.

As of the date of the filing, our available cash is not projected to be sufficient to support our operating plan for at least the next 12 months. As such, there is substantial doubt regarding our ability to continue as a going concern. We intend to seek additional capital as we prepare for the launch of Viaskin Peanut, if approved, and continue other research and development efforts. The Company will require substantial additional capital to fund its

research and development and ongoing operating expenses. The Company will seek to fund these capital requirements through debt and public or private equity before December 31, 2024.

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 to increase significantly as we develop the appropriate infrastructure to commercialize. In addition, our expenses could increase beyond expectations if the FDA requires us to perform nonclinical studies, clinical trials or post-approval clinical trials for our approved products, if any, in addition to those that we currently anticipate.

As of December 31, 2022 December 31, 2023, our cash and cash equivalents were $209.2 million. $141.4 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, as well as our plans and assumptions, we expect that our current balance of cash and cash equivalents of $141,4 million as of December 31, 2023 will be sufficient to fund our operations for at least the next 12 months. until December 31, 2024.

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.

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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 April 12, 2023 granted authority to our board of directors to increase our share capital up to 100% of issued share capital, if the investors in such offering fit within categories of persons meeting certain characteristics. In this case securities cannot be sold in such an offering at a price that is more than a 15% discount to (i) the last closing price of the Company's shares on the regulated market Euronext Paris during prior to the last trading session, date on which the issue price is set, (ii) the volume-weighted average (in the central order book and off-market blocks) price of the Company's share price of the Company on the regulated market of Euronext Paris regulated market during over a period determined by the last three trading days, (iii) the average Board of Directors of between one to five consecutive trading days chosen among from the last thirty trading sessions, or (iv) the weighted average trading price the day, each of (i) to (iv) days prior to the date on which the issue price is set.

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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 and the Israel-Hamas war, 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

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unemployment, economic slowdown and extreme volatility in the capital markets. As a result of the COVID-19 pandemic, our ability to conduct clinical trials was affected. Future pandemics, epidemics or other public health crises (collectively, "public health crises") could have an impact on our ability to conduct clinical trials, and clinical site initiation, subject enrollment and subject visits (including food

challenges) in any of our clinical trials may be suspended or delayed due to prioritization of hospital resources toward responding to such public health crises. Some participants may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers may adversely impact our future clinical trial operations. The COVID-19 pandemic and related government and private sector responsive actions affected, and any future public health crises could affect, the broader economies and financial markets, triggering an economic downturn, which at points adversely affected or could adversely affect, our ability to access capital, which could negatively affect our business. In addition, the recession or resulting adverse impacts on the capital markets resulting from the COVID-19 pandemic, and any future public health crises, could materially affect our business.

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.

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

It is impossible to predict all effects and the ultimate impact of any public health crises, including the COVID-19 pandemic. The full extent the impact of any future public health crises on our clinical development and other operations and financial performance depends on continuing developments that are uncertain and unpredictable, including the timing of any future vaccine development and rollouts and herd immunity, virus mutations and variants, and any new information that may emerge concerning future virus, vaccines, and containment, all of which may vary across regions. Any of these factors could have a material adverse impact on our business, financial condition, operating results, and ability to execute and capitalize on our strategies.

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 Separately, in early October 2023, Hamas, a militant group in control of Gaza, and Israel began an armed conflict in Israel, the Gaza Strip, and surrounding areas, which threatens to spread to other Middle Eastern countries, including Lebanon, Syria, and Iran. The Hamas-Israel military conflict is ongoing, and its length and outcome are highly unpredictable. Any or all of the effects of these effects conflicts could disrupt our and our collaborators' supply chains and adversely affect our and our collaborators' ability to conduct ongoing and future clinical trials of our product candidates. The extent and duration of the military action, sanctions and resulting economic, market and other disruptions are impossible to predict, but could be substantial. Any such disruptions may magnify the impact of the other risks described in this report.

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 scope, progress in, results and the costs of, our pre-clinical studies and clinical trials and other research and development programs, particularly as we seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;
- the approval of Viaskin Peanut by the FDA, European Commission, or other comparable regulatory authorities;

- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval, especially in North America;
- the costs of securing manufacturing arrangements for commercial production;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval;
- the scope, prioritization and number of our research and development programs;

- the costs, timing and outcome of regulatory review of our product candidates;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements, and any additional collaboration agreements we may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under our existing collaboration agreements and future collaboration agreements, if any; and
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights.

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

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

As a U.S. public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. We are subject to the reporting requirements of the 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

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, without limitation, Viaskin Milk, and our commercial opportunities may be limited.

We are currently conducting VITESSE, a Phase 3 pivotal study in in children aged 4-74 through 7 years old of age with confirmed diagnosis of peanut allergy with Type V Viaskin Peanut System, of or the modified Viaskin Peanut system. Additionally, we intend to carry out two additional Phase 3 safety studies in response to the FDA's request regarding the size of the controlled safety database. One study will be conducted in peanut allergic children 4 through 7 years of age using the Type Viaskin Peanut System (mVP), and the other will focus on peanut allergic children 1 through 3 years of age with the Type IV Viaskin Peanut System (the original Viaskin Peanut system, which will need to have positive or cVP). Positive results in order all these studies are imperative 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 are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be approved by relevant regulators or will be successfully developed or commercialized.

In addition, in some jurisdictions such as the EU, initiating Phase 3 clinical trials, including clinical trials in the pediatric population, is subject to a requirement to obtain approval 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; 51

- the FDA or the applicable foreign regulatory authority may find the data from pre-clinical studies and clinical trials from a product candidate insufficient to demonstrate that the clinical or other benefits of such product candidate outweighs its respective safety risks;
- the FDA or the applicable foreign regulatory authority may disagree with our analysis or interpretation of data from our pre-clinical studies and clinical trials;
- the FDA or the applicable foreign regulatory authority may 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;
- 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 authority may require development or implementation 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

our product candidates based on our Viaskin technology platform. Moreover, because our business is almost entirely dependent upon our Viaskin technology, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

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

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

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

- a product candidate is ineffective, inferior to existing approved medicines or treatment options, unacceptably toxic, or has unacceptable side effects;

- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested, especially during the double-blind, placebo-controlled food challenges;

- extension studies on long-term tolerance could invalidate the use of our product, showing Viaskin does not generate a sustained protective effect;

- the results may not confirm the any positive results of earlier testing or trials may not be confirmed by results of subsequent trials; and

- the results may not meet the level of statistical significance required by the FDA or other comparable regulatory authorities to establish the safety and efficacy of our product candidates.

The results of pre-clinical studies do not necessarily predict clinical success, and larger and later-stage clinical trials may not produce the same results as earlier-stage clinical trials. As a result, we may not observe a similarly favorable safety and efficacy profile as our prior clinical trials. For example, in August 2020, we received a Complete Response Letter, or CRL, in which the FDA indicated it could not approve the Viaskin Peanut BLA in its current then-current form. The FDA identified concerns regarding the impact of system adhesion on efficacy and indicated the need for modifications, and a new human factors study. studies. The FDA also indicated that supplementary clinical data would need to be generated to support applications for both the Type IV Viaskin Peanut System (the original Viaskin Peanut system), or cVP, and the Type V Viaskin Peanut System (the modified product, Viaskin Peanut System), or mVP, 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

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 many of 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. procedure at various points in our clinical trials. This consists of giving the offending food protein to patients subjects to assess the sensitivity of their food allergy to determine eligibility to participate and thus to 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 subjects who participate in our clinical trials and experience any such serious or fatal reactions. Any of the foregoing could have a material adverse effect on our business, prospects, stock price or financial condition.

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

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs, and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;
- obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials;
- manufacturing sufficient quantities of a product candidate;
- obtaining timely responses from and permission to proceed from the FDA under an 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 issued by EU Member States including input from the national competent authority and Ethics Committee, to conduct a clinical trial at a prospective clinical trial site;

- determining dosing and clinical design and making related adjustments; and

- patient subject enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients participants 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. trial.

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

- lack of effectiveness of product candidates during clinical trials;

- adverse events, safety issues or side effects relating to the product candidates or their formulation;

- serious adverse events relating to the double-blind, placebo-controlled food challenge procedure when testing patients participants 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; 54

- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;

- governmental or regulatory delays, changes by regulatory agencies, including, without limitation, unexpected changes, unrelated to new developments of the science, in prior guidance and instruction provided to us, changes in regulatory requirements, policy and guidelines, including and mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;

- failure of our collaborators to advance our product candidates through clinical development;

- delays in patient enrollment, variability in the number and types of patients subjects available for clinical trials, and lower-than anticipated retention rates for patients subjects in clinical trials;

- difficulty in patient subject monitoring and data collection due to failure of patients subjects to maintain contact after treatment;

- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as the COVID-19 pandemic or any other pandemic, terrorist activities or war, or a natural disaster; and

- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as the COVID-19 pandemic or any other pandemics, epidemics, or global health crises, terrorist activities or war, or a natural disaster; and

- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory authorities.

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

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

In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, resource constraints or changes in resources at the regulatory agencies tasked with reviewing our submissions, resulting in delays in receiving timely and consistent guidance, or changes in FDA or other similar foreign regulatory authority policy

or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn, varied or suspended. Delays or failures in obtaining regulatory approvals may result in:

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

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

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

- withdrawals, variations or suspensions of regulatory approvals; and
- fines, civil penalties, and criminal prosecutions.

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

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

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

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

We have obtained Fast Track designation from the FDA for the development of Viaskin Peanut and Viaskin Milk, and we may pursue apply for that designation for other product candidates as well. If a product is intended for the

treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation. The FDA has broad discretion to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do have Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Generally, a Fast Track designation affords the possibility of rolling review, enabling the FDA to review portions of our marketing application before submission of a complete application . application. The FDA may withdraw fast track designation if it elieves 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.

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, without limitation, the U.S. Department of Justice, and comparable foreign regulatory authorities closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and

comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, market any of our product candidates for which we, or they, receive regulatory approval for treatment other than their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the 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 or milestones for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of regulatory approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;

- our receipt of approvals, if any, by the FDA and other comparable foreign regulatory authorities and the timing thereof;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility

criteria;

- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing, as well as sales and marketing activities; and
- impacts of the COVID-19 pandemic. activities.

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

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

We are dependent on third parties for the supply of various materials, chemical or biological products that are necessary to produce Viaskin patches for our clinical trials, or diagnosis patches, and will be necessary need to depend on third parties to produce patches for our commercial supply, if Viaskin Peanut is approved. The supply of these materials could be reduced or interrupted at any time, including, without limitation, as a result of impacts due to the COVID-19 pandemic pandemics, epidemics or other global health crises, natural disasters, new laws or regulations applicable to us or our suppliers, or other unfavorable global economic conditions, including as a result of the ongoing conflict between Russia Russia-Ukraine, Israel-Hamas and Ukraine. other global political or military conflicts. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If key suppliers or manufacturers are lost or the supply of materials is diminished or discontinued, we may not be able to continue to develop, manufacture and market our product candidates or products, if any, in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products, if any, in a cost-effective 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

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 clinical trials may be delayed. Further, we are aware that Sanofi has Sanofi's strategic alliance partner, Regeneron, entered into a clinical collaboration with Regeneron and Aimmune Therapeutics, to evaluate treatment with Palforzia in combination with Dupilumab in peanut allergic patients, and patients. Regeneron 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 or to do so on acceptable terms. Even if Sanofi is able to meet our commercialization needs or if we are able to establish agreements with other third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;

- the possible misappropriation of our proprietary information, including our trade secrets and know- how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.
    - 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 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 or availability of products based on our product candidates into the market. Moreover, the constituent parts of a combination product retain their regulatory status (as a biologic or medical device, for example) and, as such, we or our contract manufacturers may be subject to additional requirements in the 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;

- 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 . 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 administrated more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

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

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

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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. Marketing Authorization. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

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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 are,or any collaborator is, unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives regulatory approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;

- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the product;
- the market price of our product relative to competing treatments; and
- our ability to effectively implement a scientific publication strategy.

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

The biopharmaceuticals industry is highly competitive. Numerous biopharmaceutical and biotechnology companies, universities and other research entities are actively involved in the discovery, development and

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

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

Studies combining other methods of allergen immunotherapy, such as OIT, with anti-IgE monoclonal antibodies treatments (anti-IgE and anti-IL-4Rα) as adjunct therapy are being conducted currently. These types of co-administrations may significantly improve the safety of specific allergen immunotherapies administered orally or subcutaneously. 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 as monotherapy or in combination with allergen immunotherapy, may become significant competitors with to our products. On February 16 2024, the FDA approved Xolair® (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy.

There is one treatment that is specific for peanut allergy, a proprietary form of OIT which has been was 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 2020, and divested the Palforzia business to function as a stand- alone business unit that will manage all of Nestlé's global pharmaceutical business. Stallergenes Greer in September 2023.

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 product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate

that covers our costs, including research, development, manufacture, sales and distribution. Third-party payors are increasingly reducing reimbursements for medical products, drugs and services. 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- existingpre-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 the Biden administration'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. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenge. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, In response to the Biden administration released an additional administration’s October 2022 executive order, on October 14, 2022 February 14, 2023, directing HHS to submit released a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test outlining three

new models for lowering drug costs for Medicare testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and Medicaid beneficiaries. improve quality of care. It is unclear whether this executive order or similar policy initiatives the models will be implemented utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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.

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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.

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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 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

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 any future ICER report or any similar recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use or reimbursement of Viaskin Peanut, if approved, could have a material adverse effect on our results of operations and financial condition. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of Viaskin Peanut, if approved, could adversely affect the market price of our securities.

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

Our product candidates are being developed to address the needs of allergic patients, for some of whom they can have a profound and life-threatening adverse reaction if exposed to even minute amounts of an allergen. Accordingly, safety is of paramount importance in developing these product candidates. To date, more than twelve clinical trials of Viaskin Peanut and Viaskin Milk product candidates have been conducted both outside and inside of the United States in over 1,000 human patients subjects to evaluate the safety and efficacy of these product candidates for the treatment of peanut allergies and milk allergies, respectively. Adverse events observed in these clinical trials have primarily involved general disorders such skin and subcutaneous tissue, immune system and administration site conditions, such as erythema, pruritus, edema and urticaria. However, in clinical trials to date, one case of mild to moderate anaphylaxis has been reported, and it is possible that anaphylaxis or other systemic reactions may occur in the future. It is worth noting that, as a desensitization patch bringing the allergen into contact with the skin, reactions, which are a source of itching and discomfort for the patient, subjects, are common. This

reaction is typically temporary in duration and fades after a few weeks of use. In addition, during daily administration of the patches during treatments, depending on the severity of the allergies and patient subject response to treatment, precautionary measures are necessary when handling the patches after use due to risk of contamination.

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

other similar products) after 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 Brexit, 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 encompasses 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 On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so-called "Windsor Framework". The Framework is currently unclear intended to what extent revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will seek be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK-only regulatory environment under the authority of the MHRA with respect to align its regulations all medicinal products. The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the EU supply of medicinal products into Northern Ireland anticipated to take effect 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. 2025.

Since a A significant proportion of the regulatory framework in the UK which may be applicable to our business and our product candidates medicinal products is currently derived from EU Directives and Regulations, Regulations. The potential for UK legislation to diverge from EU legislation following Brexit following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, import, approval, and commercialization of our product candidates in the UK or the EU, now that UK legislation has EU. If we are slow or unable to adapt to changes in existing requirements or the potential to diverge from EU legislation. adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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.

- 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 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

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 has become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments 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 UK Government published its response 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 on March 21, 2023 confirming that it would bring forward changes to the legislation. These resulting legislative amendments will determine whether how closely the UK chooses to regulations will align with the regulation or diverge from it to maintain regulatory flexibility. A decision by CTR. Failure of 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, and comparable regulatory authorities', guidance and regulations truthful and non-misleading information that is consistent with, but not contained in, the product's approved labeling. If we are found to have promoted off-label uses or promoted our product before approval, we may become subject to significant liability under the FDCA and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA and other U.S. government agencies has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the marketing of Viaskin patch products, if approved, by restricting off-label promotion, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Similar limitations and penalties are provided in the EU both at EU level and at national level in individual EU Member States.

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

The success of our business depends primarily upon our ability to identify, develop and commercialize products to treat food allergies. In addition to Viaskin Peanut, we may pursue development of our other development programs, including Viaskin Milk. None of our other product candidates and potential product candidates has commenced any clinical trials since we scaled down our research and clinical development efforts in 2020 and 2021 to focus on Viaskin Peanut. There are a number of FDA or foreign requirements that we must satisfy before we can commence clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. We may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of our other potential product candidates, such

product candidates may never be approved by the FDA or comparable foreign regulatory authorities. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

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

A key aspect of our current strategy is to selectively enter into collaborations with third parties to conduct clinical testing. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We currently have multiple collaboration agreements in effect, including collaborations for the development of applications in the field of respiratory allergies or autoimmune disease, as well as other therapeutic domains, such as vaccines. Collaboration agreements such as our exclusive global collaboration with Nestlé 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;

- 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 protect, encompass, or embody commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;

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

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process and after a patent grants. There may also be significant expenses associated with enforcing and/or defending various patents in a patent portfolio. 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. jurisdiction (perhaps irrevocably). If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

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

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

The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related

patent claims. The standards of the 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 proceedings; U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. USPTO (collectively, "post-grant proceedings"). Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, 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 United States Court of Appeals for the Federal Circuit, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the

standards of patentability and any such changes could have a negative impact on our business. For example, recently the federal courts and the United States Supreme Court have issued (or will issue) (and may issue additional) 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""first-to-invent" system to a "first-to-file""first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed and prosecuted during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed (and continues to develop) new and untested, or relatively lightly tested, regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is 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 bene proposed that, if passed, would make changes to the America Invents Act. For example, bills have been introduced that would reduce the discretion of the Patent Trial and Appeal Board (PTAB) to deny some or all post-grant review. proceedings. In addition, bills, rules and/or regulations 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 and become law, they could impact our ability to enforce/defend patents by allowing third parties more opportunities to challenge them. patents.

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

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

party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

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

misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

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

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

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. parties under certain circumstances. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time- consuming 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 or other intellectual property rights, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us.

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

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

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

- us or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business and financial condition. As a result, we could be prevented from commercializing current or future product candidates.

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

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

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

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity 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.
    - in the case of trademark claims, redesign, or rename, Viaskin™ or other trademarks we may own, to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

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

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

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our product candidate, the defendant could counterclaim that the patent covering our product candidate is invalid

and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations of lack of candor or good faith in dealing with USPTO, that someone connected with prosecution of the patent withheld relevant and/or materials 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, inter partes review, and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover, encompass, or protect our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. If a party were to prevail on a legal assertion of unenforceability, such a holding could also affect other related patents. Such a loss of patent protection would have a material adverse impact on our business.

Risks Related to Our Organization, Structure and Operations

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

Our success depends to a significant degree upon the technical and management skills of our officers and key personnel. The loss of the services of any of these individuals would likely have an adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our key executives could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain marketing approval of and commercialize products.

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to: comply with the regulations of the FDA and applicable foreign regulatory authorities, provide accurate information to the FDA and applicable foreign regulatory authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range

of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on,

information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical products. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient's condition, injury or even death. For example, product liability claims may be brought by patients subjects participating in our clinical trials as a result

of unexpected side effects from our product candidates. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, the regulatory authorities, other biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we may be forced to limit or forgo further commercialization of the affected products.

We may incur significant costs from class action litigation.

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

For example, in December 2018, we announced that we voluntarily withdrew our BLA for Viaskin Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls, and our ADS price declined significantly as a result. Following this announcement, a class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey.

The complaint, as amended, alleged Jersey alleging that we and our former Chief Executive Officer, our current Chief Executive Officer, our former Deputy Chief Executive Officer, and our former Chief Business officer 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 a plaintiff's claims are successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating

results and financial condition. We maintain liability insurance; however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

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

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

Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our 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. $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 $8.9 millions and $7.5 million, $5.7 millions, as of December 31, 2022 December 31, 2023 and 2021 2022 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 results of 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

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; actions, litigation, fines and penalties; penalties, disruptions of our business operations; operations, reputational harm; harm, loss of revenue or profits; 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 has expanded 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 become

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 the total annual global revenue of the preceding year, whichever is greater. Furthermore, companies may face private litigation related to processing of personal data brought by data subjects, 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. States on a long-term basis. 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. The European Commission adopted an adequacy decision for the EU-US Data Privacy Framework, or DPF, on July 10, 2023, further to the Biden Administration's Executive Order dated October 7, 2022 which provides that entities in the EEA may transfer personal data to entities in the United States that adhere and comply with the DPF without having to implement additional safeguards. However, the DPF is may not provide adequate protection given the previous successive invalidations of previously EU-US adequacy mechanisms and the periodic review of the DPF by the European Commission does not consider to provide an adequate level of data privacy and security. Commission. 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 These SCCs are can be a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the EEA. However, only entering into SCCs will remain a valid mechanism. Additionally, the SCCs impose may not be sufficiency and additional compliance burdens are required, 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.

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; payment of damages; 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; actions, litigation, fines and penalties; penalties, disruptions of our business operations; operations, reputational harm; harm, loss of revenue or profits; 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

increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Additionally, the COVID-19 pandemic our workforce's use of network connections, computers, and devices outside our remote workforce premises or networks, including working remotely from home, while in transit, and in public locations, poses increased risks to our information technology systems and data, 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. data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not previously identified while conducting due diligence acquired or integrated entities and it may be difficult to integrate companies into our information technology environment and security program.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to sensitive information held by us or our information technology systems, or those of the third parties 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

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

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the 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 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 December 31, 2023, we had 85 104 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 $0.70 and as high as $3.43 $2.23 during 2022. 2023. During this same period, our ordinary share prices have ranged from as low as €2.17 €1.40 to as high as €5.48. €4.07. 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.

conditions. These and other market and industry factors may cause the market price and demand for our securities to

fluctuate substantially, regardless of our actual operating

performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

As of December 31, 2022 December 31, 2023, 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% 47% 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.

On December 20, 2023, we received a letter from the Listing Qualifications Staff of Nasdaq notifying the us that for the last 30 consecutive business days, the bid price of our ADSs had closed below $1.00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until June 17, 2024, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our ADSs must be at least $1.00 per share for a minimum of 10 consecutive business days before the expiration of the 180-day period. To regain compliance, during the 180 day period the minimum bid price of our ADSs must close at $1.00 per share or more for a minimum of 10 consecutive business days. If we do not regain compliance with the Nasdaq Listing Rules prior to the expiration of the 180-day compliance period, we may be eligible for additional time to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(ii).

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

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

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

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

Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs. Investors seeking cash dividends should not purchase the ADSs. Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our annual financial statements. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

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

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

As of December 31, 2022 December 31, 2023, 94,137,145 96,431,770 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 $194 million PIPE financing (the "June 2022 PIPE") 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 June 2022 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 June 2022 PIPE, financing, including ordinary shares underlying the pre-funded warrants. As a result, subject to certain beneficial ownership

limitations contained in the pre-fundedpre- 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;
    - 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 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 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;

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;
    - 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.

- pursuant to French law, the sections of the by-laws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by at least a two thirds majority vote of our shareholders present, represented by a proxy or voting by mail at the meeting.

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

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise

of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

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

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

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis, transferable during a period starting two days prior to

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

According to French law, as of December 31, 2023 we have issued :

- 28,276,331 pre-funded warrants at a pre-funded price per pre-funded warrant of €2.90 (corresponding to $3.11), Each pre-funded warrant bears an exercise price of €0.10 per Warrant Share;

- Restricted Stock Units (“RSU”), stock options plan (“SO”), and non-employee warrants (Bons de Souscription d’Actions i.e. “BSA”) representing globally 9,458,901 outstanding shares as of December 31, 2023.

The exercise of some or all pre-funded warrants, RSU, SO and non-employee warrants will increase the number of outstanding ordinary shares, which may dilute the ownership percentage or voting power of shareholders by 9,8% (without pre-funded warrants exercise, and 39,1% should all pre-funded warrants be exercised).

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, or (d) for individuals who are not nationals of a Member State of the EU or of a State party to the agreement on the EEA that has entered into an administrative assistance agreement with France and/or are not domiciled in one of these State, or for legal entities of which at least one of the members of the control chain is not governed by the law of one of these States or is not a national and/or is not domiciled there, to cross the threshold of 10% of the voting rights of a French company whose shares are admitted to trading on a regulated market and (iii) whose activities concern, even occasionally, the research and development of so-called critical technologies, such as biotechnologies, and considered essential to the protection of public health, is subject to prior authorization by the French Minister of the Economy (*Ministère de l'Economie*).

In addition, French Decree (*Décret*) No. 2020-892 of July 22, 2020 as amended by The French Decree No. 2020-1729 2023-1293 of December 28, 2020, French Decree No. 2021-1758 of December 22, 2021 and December 28, 2023 has made permanent the temporary regime under French Decree No. 2022-1622 of December 23, 2022 (i) lowers the scope of application of the foreign investment regime until , which expired on December 31, 2023 to the .

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 is subject to a fast track review procedure (filing of a simplified form, delay for the Minister to respond limited to 10 days, transaction deemed authorized in the absence of a response at the end of the delay).

If an investment in the Company requiring the prior authorization of the Minister of the Economy is made without such authorization having been granted, the Minister of the Economy may cancel the transaction or order (possibly under financial penalty) the investor concerned (i) to submit an application for authorization, (ii) to have the previous situation restored at its own expense or (iii) to modify the investment. In addition, the Minister may impose undertakings and conditions on the investor (including regular reporting commitments). The investor concerned could also be declared criminally liable and be sanctioned, in particular, by exclusion from any public contract or by a fine which may not exceed the highest of the following three amounts: (i) twice the amount of the investment concerned, (ii) 10% of the Company's annual pre-tax revenues and (iii) 5 million 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, subsidiaries, are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a

claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

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

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

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

We are currently a "smaller reporting company" as defined in the 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 $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 $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 $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 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. 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 December 31, 2023. 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 shareholder that is a United States person for U.S. federal income tax purposes, or 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, holders, the addition of interest charges to the tax on such gains and certain distributions, and additional reporting requirements.

A U.S. holder in certain circumstances may mitigate the adverse tax consequences of the PFIC rules by filing an election to treat the PFIC "qualified electing fund", or 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 December 31, 2023, we have provided that information. However, there is no assurance that such information will be provided in future taxable years, and prospective investors should not assume that a QEF election will be available.

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

92Risk management and strategy

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

Our Information Systems function, led by our Vice President for Information Systems and Director of Information Systems, helps identify, assess and manage the Company's cybersecurity threats and risks. Our

Information Systems function identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example automated tools, subscribing to and analyzing reports and services that identify cybersecurity threats, conducting scans of the Company's threat environment, evaluating threats that are reported to us, conducting internal audits, internal threat assessments, and conducting vulnerability assessments.

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

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

and management documentation is updated annually, and our Information Systems function, led by our Vice President for Information Systems and Director of Information Systems, prepares cybersecurity roadmaps designed to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

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

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

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including ***If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.***

Governance

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

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including Cyril Guyardeau, our Director of Information Systems Security, who had previously spent 15 years as an IT infrastructure engineer in the healthcare industry, and Cecile Delansorne, our

Vice President for Information Systems, who has held similar executive positions overseeing information systems in other pharmaceutical companies for over 7years. Our Vice President for Information Systems reports to our CFO.

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

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

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

Item 2. Properties.

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy office occupies 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 on July 31, 2024.

The company leased a commercial facility in Chatillon, France with early availability of the premises from November , 2023 and commencement of the lease on April 16, 2024. Our principal offices will represent 2 446,7 square meter facility.

Our primary U.S. 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 replead 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 Compliant 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 March 6, 2024, there were approximately 395 402 holders of record of our ordinary shares and 2 65 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 December 31, 2023, 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

- dividends, reclassifications and On March 23, 2023, the like. The pre-funded warrants issued in the PIPE provide that the holder issuance of the pre-funded warrants will not have the right to exercise any portion an aggregate of its pre-funded warrants if such holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of 10,174 ordinary shares outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"). The holder may increase or decrease U.S. and on-U.S. employees upon settlement of RSUs;
- On May 29, 2023, the Beneficial Ownership Limitation, provided, however, that the holder may only increase the Beneficial Ownership Limitation by (i) obtaining authorization from the French Ministry issuance 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 an aggregate 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 2,500 ordinary shares issued in to a non-U.S. employee upon settlement of RSUs;
- On May 22, 2023, the PIPE financing, including issuance of an aggregate of 14,364 ordinary shares underlying to non-U.S. employees upon settlement of RSUs;
- On May 24, 2023, the pre-funded warrants. issuance of an aggregate of 34,321 ordinary shares to U.S. and non-U.S. employees upon settlement of RSUs;
- On September 23, 2023, the issuance of an aggregate of 2,599 ordinary shares to U.S. and non-U.S. employees upon settlement of RSUs

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™, EPITTM, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin, an epicutaneous patch (i.e., a skin patch). We have generated significant data demonstrating that Viaskin's mechanism of action is novel and differentiated. Viaskin targets specific antigen-presenting immune cells in the skin, called Langerhans cells, that capture the antigen and

migrate to the lymph node in order to activate the immune system without passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to treat children suffering from food allergies, for whom safety is paramount, since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as anaphylactic shock. We believe Viaskin may offer convenient, self-administered, non-invasive immunotherapy to patients, if approved.

Our most advanced product candidate is Viaskin Peanut, which has been evaluated as a potential therapy for children with peanut allergy in nine twelve clinical trials, including four three Phase 2 trials and three four completed Phase 3 trials. We recently completed a have two ongoing 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 $141.4 million as of December 31, 2022 December 31, 2023 will be sufficient to fund its operations until December 31, 2024.

The company has incurred operating losses and negative cash flows from operations since inception.

As of the date of the filing, our available cash is not projected to be sufficient to support our operating plan for at least the next 12 months. As such, there is substantial doubt regarding our ability to continue as a going concern. We intend to seek additional capital as we prepare for the launch of Viaskin Peanut, if approved, and continue other research and development efforts. The Company will require substantial additional capital to fund its research and development and ongoing operating expenses. These capital requirements are expected to be funded through debt and equity offerings before December 31, 2024.

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 resulting from geopolitical instability, macroeconomic conditions, global health crises, 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. other factors.

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;
    - continue our research, pre-clinical and clinical development of our product candidates, in particular 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;
    - 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;
    - acquire or in-license other product candidates and technologies;
- make milestone or meet other payments deadlines under any in-license agreements;
    - 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;
  - 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

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 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 Research and development 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 December 31, 2023, we spent $75.5 million $60.2 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 December 31, 2023 and 2021, 2022, 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, 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 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 compensation expense	$ 73,241	$ 68,690
Share-based compensation expenses included in research and development expenses	$ 2,303	$ 1,646
Total research and development expenses	**$ 75,543**	**$ 70,336**

	Year Ended December 31,	
	2023	2022
	(thousands of U.S. Dollars)	
Research and development expenses related to Viaskin Peanut(1)	$ 60,329	$ 47,766
As a percentage of research and development expenses, excluding share-based compensation Expense(2)	105%	65%
Research and development expenses related to Viaskin Milk(1)	$ 6,019	$ 8,180
As a percentage of research and development expenses excluding share-based compensation Expense(3)	10%	11%
Other research and development expenses(1)	$ (8,621)	$ 17,295
Total research and development expenses, excluding share-based compensation expense	$ 57,727	$ 73,241
Share-based compensation expenses included in research and development expenses	$ 2,496	$ 2,303
Total research and development expenses	**$ 60,223**	**$ 75,543**

(1) Excludes employee share-based compensation expense. expense after $19,9 millions loss on completion accrual reversal as of December 2023.

(2) If we exclude Mag1c impact the percentage of research and development expenses related to Viaskin Peanut in 2023 would be 84%

(3) If we exclude Mag1c impact the percentage of research and development expenses related to Viaskin Milk in 2023 would be 8%

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;

- 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, 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 any collaboration agreements and or future collaboration agreements, collaborations, 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 2023 or 2021. 2022.

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.

If a company meets certain criteria in terms of sales, headcount or assets to be considered a Small and Medium-sized 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. $26.1 million. During the fiscal year ending December 31, 2023, the Company received the reimbursement of the 2022 fiscal year research tax credits for a total amount of $5.9 million.

Collaboration agreement Agreement with Nestlé Health Science

On May 31, 2016, In May 2016, we announced our entry entered into a Development Collaboration and License Agreement (the "Collaboration Agreement") with Société des Produits Nestlé S.A. (formerly NESTEC S.A.) ("NESTEC"). The Collaboration Agreement

related to an exclusive global collaboration with Nestlé Health Science to develop for the development and, if approved, commercialization of MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of cow's milk protein allergy CMPA (non-mediated IgE) in infants and toddlers. infants.

Under the terms of the exclusive collaboration, we are Collaboration Agreement, the Company was responsible for leading the development activities of MAG1C up through a pivotal Phase 3 clinical program, and if the appropriate regulatory approvals are were received, Nestlé Health Science will would 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 globally. The Company was eligible to receive up to €100.0 million millions ($105.0 millions at December 31, 2023 closing exchange rate) in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable including an upfront payment of €10.0 million that we millions received in July 2016.

Our current clinical trials, On October 30, 2023, the Company and NESTEC entered into a Mutual Termination Letter Agreement terminating the Collaboration Agreement. Each party remains responsible for its own costs and expenses related to its respective wind-down activities. Any and all licenses and sublicenses, granted by either party to the other party under the Collaboration Agreement, including, without limitation, any licenses to intellectual property, were revoked and terminated.

Consequently, since signing the Phase 2 clinical trial conducted Mutual Termination Letter Agreement and as part of December 31, 2023, we recorded the following :

- Loss on completion accrual reversal $19,9 millions (Other Operating Income);
- Deferred revenue accrual reversal $6.9 millions (Operating Expenses);
- Accrual for ongoing Clinical study completion $2.3 millions (Operating Expenses). This accrual represents our best estimate 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 remainder expenses related to the Phase 2 ongoing 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 study which will be incurred after December 31, 2023 and until the end 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. study.

Operating Expenses

Since our inception, our operating expenses have consisted primarily of research Research and development Development activities, general General and administration Administration costs and to lesser extent 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 Development expenses comprise clinical trials direct costs including as well as salaries, share-based payments and benefits for research internal Research and development personnel, outside consultants, Development personnel. Consultants, costs of clinical trials

costs related to manufacturing clinical study materials, sponsored research, clinical trials insurance, other outside external costs, depreciation (of Research and Development equipments and other depreciation related to Research and Development like loss on completion on MAG1C study), 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 Research and development 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. Union. We anticipate that our sales and marketing expenses will increase significantly in the future as we prepare for the potential launch and commercialization of Viaskin Peanut in North America and in the European Union, if approved.

General and Administrative

General and administrative expense consists Administrative expenses consist primarily of personnel costs and including share-based compensation for finance, legal, Finance, Legal, IT, Human Resources and administrative other Administrative employees. General and administrative Administrative expense also consists of costs related Information Systems architecture, software licenses, IT equipment and, 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 General and administrative Administrative expenses will increase in the future as we increase our headcount to support the expected growth in our research Research and development 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 short term remaining maturity at the date of purchase of three months or less, allowing refundable within one month, for which the funds risk of changes in value is considered to be freely withdrawn at any time without significant penalty. insignificant. 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 December 31, 2023 and 2021 2022

The following table summarizes our the results of our operations, derived from our consolidated financial statements, prepared in compliance with generally accepted accounting principles in the United States, or U.S. GAAP, for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

(Dollar amounts presented in thousands, except per share amounts)	December 31, 2022	December 31, 2021	$ change	% change
Operating income	**$ 4,844**	**$ 5,708**	**(864)**	**(15)%**
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%)
Total Operating expenses	(101,475)	(104,323)	2,848	(3%)
Financial income (expense)	427	425	2	1%
Income tax	(70)	381	(451)	(118%)
Net loss	**$ (96,274)**	**$ (97,809)**	**1,535**	**(32%)**
Basic/diluted Net loss per share attributable to shareholders	(1.24)	(1.78)		

(Dollar amounts presented in thousands, except per share amounts)	December 31, 2023	2022	$ change	% change
Operating income	**$ 15,728**	**$ 4,844**	**10,885**	**225 %**
Operating expenses				
Research and development expenses	(60,223)	(75,543)	15,320	(20 %)
Sales and marketing expenses	(2,438)	(1,608)	(830)	52 %
General and administrative expenses	(29,500)	(24,324)	(5,176)	21 %
Restructuring income (expenses)	—	—	—	—
Total Operating expenses	(92,161)	(101,475)	9,314	(9 %)
Financial income (expense)	3,714	427	3,286	769 %
Income tax	(7)	(70)	63	(90 %)
Net loss	**$ (72,726)**	**$ (96,274)**	**23,548**	**(24 %)**
Basic/diluted Net loss per share attributable to shareholders	(0.76)	(1.24)		

Operating Income

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

(Dollar amounts presented in thousands)	December 31, 2022	2021	$ change	% change	December 31, 2023	2022	$ change	% change
Sales	—	—						
Other income	4,844	5,708	(864)	(15)%	15,728	4,844	10,884	225 %
Research tax credit	*5,718*	*7,505*	(588)	(24 %)	*8,766*	*5,718*	*3,048*	*53 %*
Other operating (loss) income	*(874)*	*(1,797)*	923	(51 %)	*6,962*	*(874)*	*7,836*	*(896 %)*
Total operating income	**4,844**	**5,708**	(864)	**(15)%**	**15,728**	**4,844**	10,884	**225 %**

We generated operating income of $4.8 million $15.7 millions for the year ended December 31, 2022 December 31, 2023 compared to $5.7 million $4.8 millions for the year ended December 31, 2021, a decrease of 15% December 31, 2022. The decrease increase in operating income is mainly attributable due to the decrease increase in research tax credit eligible basis (studies ending in the course of 2022) and the change in revenue recognition of $6.9 millions related to the deferred revenue recognized under following the Nestlé's collaboration agreement, as we updated the measurement of progress termination of the Phase 2 clinical trial conducted Collaboration Agreement with Nestlé.

Research tax credit increased by $3.0 millions for the year ended December 31, 2023 compared to the year ended December 31, 2022 as part a result of the agreement due extension of the eligible expense base to delays in new patient enrollment. The decrease in include clinical supplies. A corrective Research tax credit was filed by the Company for $2.9 millions for 2020, 2021 and 2022 fiscal year research tax credit is attributable during the year ended December 31, 2023.

Other operating income increased by $7.8 millions for the year ended December 31, 2023 compared to the decline in eligible expenses in connection with research year ended December 31, 2022 mainly due the reversal of deferred revenue following the Mutual Termination Letter Agreement, effective October 30, 2023, of the Collaboration Agreement between the Company and development expenses. Nestlé Health Science.

Operating Expenses

Research and Development Expenses

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

(Dollar amounts presented in thousands)	December 31, 2022	2021	$ change	% change	December 31, 2023	2022	$ change	% change
Research and development expenses								
External clinical-related expenses	42,248	39,386	2,862	7%	49,044	42,248	6,796	16%
Employee-related costs excl. share-based payment expenses	10,752	12,950	(2,198)	(17%)	14,401	10,752	3,649	34%
Share-based payment expenses	2,303	1,646	656	40%	2,496	2,303	193	8%
Depreciation and amortization	12,965	9,878	3,087	31%	(13,658)	12,965	(26,623)	(205%)
Other costs	7,276	6,476	800	12%	7,940	7,276	664	9%
Total Research and development expenses	**75,543**	**70,336**	**5,207**	**7%**	**60,223**	**75,443**	**(15,320)**	**(20%)**

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 Development expenses increased decreased by $5.2 million $15.3 millions for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021. December 31, 2022 mainly as a result of :

- loss on completion accrual net reversal $17,6 millions (compared to a $10.4 millions depreciation as of December 31, 2022) resulting from Nestlé Collaboration Agreement termination, that offset;
- the global increase of $11.3 million in research and development expenses.

External clinical-related expenses increased by $2.9 million $6.8 millions for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022, primarily due to upfront fees for reflecting intensified Research and Development activities (1) after the launch initiation of Viaskin Peanut the VITESSE trial with the first patient screened in March 2023, and (2) as part of the new safety study for toddlers and children ages 4-7 during after the fourth quarter ended December 31, 2022. FDA confirmed additional safety data is required for BLA.

Employee-related costs, excluding share-based payment expenses, decreased increased by $2.2 million $3.6 million for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022 due to the workforce reduction following full implementation of increase to support research and development activities on VITESSE trial and the new organization.

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 safety study for toddlers 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. children.

Sales and Marketing Expenses

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

(Dollar amounts presented in thousands)	December 31, 2022	2021	$ change	% change	December 31, 2023	2022	$ change	% change
Sales and marketing expenses								
Employee-related costs incl. share-based payment expenses	914	1,885	(971)	(52%)	754	914	(160)	(18%)
External professional services and other costs	694	2,502	(1,808)	(72%)	1,784	694	990	143%
Total Sales and marketing expenses	**1,608**	**4,387**	**(2,779)**	**(63%)**	**2,438**	**1,608**	**830**	**52%**

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

Sales and marketing Marketing expenses decreased increased by $2.8 million $0.8 million for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022, primarily due to a decrease an increase in employee-related costs, external professional services, and share-based payment expenses. fees related to pre-commercialization activities for Viaskin Peanut in North America.

Employee-related costs (including share-based payments expenses) related to payroll for the U.S. and European employees, decreased by $1.0 million $0.2 million for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022, primarily due to employee departure in 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. US.

External professional services and other costs decreased increased by $1.8 million $1.0 million for the year ended December 31, 2022 December 31, 2023 compared to the year ended December 31, 2021 December 31, 2022, primarily as a result of budget discipline measures of mainly due to an increase in fees related to 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, 2022	2021	$ change	% change	December 31, 2023	2022	$ change	% change
General and administrative expenses								
External professional services fees	5,947	7,944	(1,997)	(25%)	8,750	5,947	2,803	47%
Employee-related costs excl. share-based payment expenses	7,320	8,194	(874)	(11%)	8,200	7,320	881	12%
Share-based payment expenses	2,688	1,163	1,525	131%	3,389	2,688	701	26%

Depreciation, amortization and other costs	8,369	13,219	(4,865)	(37%)	9,161	8,369	2,523	30%
Total General and administrative expenses	**24,324**	**30,520**	**(6,196)**	**(20%)**	**29,500**	**24,324**	**5,176**	**21%**

General and administrative expenses decreased increased by $6.2 million $5.2 millions for the year ended December 31, 2022 December 31, 2023, compared to the year ended December 31, 2021, primarily December 31, 2022. The source of this increase is threefold (1) an increase by $2.8 millions of external professional services fees incurred in our financing activities, (2) an increase by $0.9 million in employee-related costs to support General and Administrative activities, and (3) an increase by $0.8 million in depreciation, amortization and other costs mainly due to cost containment measures and decreased external professional fees (decreased by 2.0 million), partially offset by an increase Montrouge office revamping which will be departed for a new location in share-based payment expenses. Q2 of 2024.

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

Depreciation, amortization and other costs decreased by $4.9 million mainly due 2022 to the decrease of insurance policies by $2.7 million, mainly due to the decrease 34 employees in Directors and Officers insurance premium. 2023.

Financial income (loss)

Our financial income was $0.4 million $3.7 millions in 2022 2023 and 2021, $0.4 million in 2022, and primarily includes the financial income on our financial assets and foreign exchange gains.

Income tax

Our income tax expense was $70,000 $7,000 for the year ended December 31, 2022 December 31, 2023, compared to a US Tax income of $381,000 $70,000 for the year ended December 31, 2021 December 31, 2022.

Net loss

Net loss was $96.3 million $72.7 million for the year ended December 31, 2022 December 31, 2023, compared to $97.8 million $96.3 million for the year ended December 31, 2021 December 31, 2022. Net loss per share (based on the weighted average number of shares outstanding over the period) was $1.24 $0.76 and $1.78 $1.24 for the year ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Liquidity and Capital Resources

Financial Condition

On December 31, 2022 December 31, 2023, we had $209.2 million held $141.4 millions in cash and cash equivalents compared to $77.3 million $209.2 millions of cash and cash equivalents on December 31, 2021. We have incurred operating losses and negative cash flows from operations since our inception. December 31, 2022.. Net cash used for operating activities was $55.7 $79.6 and $108.2 million

$55.7 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we recorded a net loss of $96.3 million. $72.7 million. Our net cash flows provided by financing activities totaled $194.1 million $7.1 million in 2022, 2023, mainly consisting of the proceeds from our global offering in the second quarter of 2022. ATM program.

Sources of Liquidity and Material Cash Requirements

Based on its current operations, plans and assumptions as revised pursuant to 2022 2023 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 $141.4 million as of December 31, 2022 December 31, 2023 will be sufficient to fund its operations until December 31, 2024.

As of the date of the filing, our available cash is not projected to be sufficient to support our operating plan for at least the next 12 months. As such, there is substantial doubt regarding our ability to continue as a going concern.

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 $100 million of American Depositary 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.

Pursuant to the ATM program, we the Company issued and completed sales of new ordinary shares Ordinary Shares in the form of ADSs for a total gross amount of $15.3 million ($14.1 $15.3 million net on May 4, 2022, and of transaction costs) $7.8 million on June 14, 2023. Respectively, 6,036,238 and 2,052,450 new Ordinary Shares in the form of ADSs were 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 and $1.90 per ADS, each ADS representing giving the right to receive one-half of one ordinary shares share 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 December 31, 2023 and 2021, 2022, we obtained the following financing on the public markets by issuance of securities, net of commissions and estimated offering expenses:

	Equity capital	Bank Loans	Other debt	Total	Equity capital	Bank Loans	Other debt	Total
	(Amounts in thousands of U.S. Dollars)				(Amounts in thousands of U.S. Dollars)			
2021	—	—	—	—				
2022	194,446	—	—	194,446	194,446	—	—	194,446
2023					6,921	—	—	6,921
Total	**194,446**	**—**	**—**	**194,446**	**201,367**	**—**	**—**	**201,367**

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 any

future pandemics, epidemics or global health crises and conflict in Ukraine. Ukraine or other global political or military crises. 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 expenses commitments for future periods:

	Material Cash Requirements Due by the Year Ended December 31,				
	2023	2024	2025	Thereafter	Total
	(Amounts in thousands)				
Operating leases	2,051	1,243	71	—	3,364
Purchase obligations—Obligations Under the Terms of CRO Agreements	23,336	20,021	5,378	—	48,735
Total	25,387	21,264	5,449	—	52,099

	Material expenses Commitments Due by the Year Ended December 31,				
	2024	2025	2026	Thereafter	Total
	(Amounts in thousands)				
Operating leases	1,205	65	421	5,514	7,205
Purchase obligations—Obligations Under the Terms of CRO commitments	22,732	11,006	1,406	1,831	36,974
Total	23,937	11,071	1,827	7,345	44,179

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 Financement 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 $1.1 million cash requirement as of December 31, 2022 which expires March 8, 2024. December 31, 2023 until July, 2024.

In November, 2023, the Company entered into new agreements to relocate its headquarters in Chatillon, France:

- a short term lease agreement for the fitting works of the new offices,
- a lease agreement starting April 16, 2024 with a minimum duration of six years.

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 $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 achieved the resizing of our facility use in North America that were was initially intended to support our U.S. subsidiary as well as future commercialization needs: needs, explaining partially operating leases costs as of December 31, 2023 and December 31, 2022 :

- 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 January 2022, we concluded 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 December 31, 2023, expenses associated with the ongoing trials amounted globally to $126.1 million, $114.4 million, and we had non-cancellable contractual obligations with CRO until year ended 2025 amounting to $48.7 million. $44.2 million.

Cash flows

The table below summarizes our sources and uses of cash for the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

(Amounts in thousands of U.S. Dollars)	December 31, 2022	December 31, 2021	$ change	% change
Net cash flows used in operating activities	(55,666)	(108,242)	52,576	(49%)
Net cash flows used in investing activities	(100)	(433)	333	(77%)
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	(39%)
Net (decrease) increase in cash and cash equivalents	**131,893**	**(119,051)**	**250,944**	*

(Amounts in thousands of U.S. Dollars)	December 31, 2023	December 31, 2022	$ change	% change
Net cash flows used in operating activities	(79,653)	(55,666)	(23,982)	43%
Net cash flows used in investing activities	(808)	(100)	(1,017)	1016%
Net cash flows provided by financing activities	6,767	194,120	(187,045)	(96%)
Effect of exchange rate changes on cash and cash equivalents	5,867	(6,461)	12,328	(191%)
Net (decrease) increase in cash and cash equivalents	**(67,827)**	**131,893**	**(199,716)**	*

* *Percentage not meaningful*

Operating Activities

Our net cash flows used in operating activities were $55.7 million $79.7 millions and $108.2 million $55.7 millions in 2022 2023 and 2021 2022 respectively. Our net cash flows used in operating activities decreased increased by $52.6 million, $24.0 millions, or 49% 43%, mainly due to the reclassification collection in 2021 (from non-current assets 2022 of the research tax credit receivable relating to current assets) of the fiscal years 2019 to 2021 research tax credit that was fully reimbursed in 2022, and also due for €24.8 millions (corresponding to cost containment measures and $28.1 millions on the decrease in personnel expenses related to the workforce reduction as part basis of our 2020 global restructuring plan. 2021 closing exchange rate).

Investing Activities

Our net cash flows used in investing activities were $0.1 million $0.8 million and $0.4 million $0.1 million in 2023 and 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 decreased to $194.1 million $6.8 millions in 2022 2023 from $0.3 million $194.1 millions in 2021. 2022. For the year ended December 31, 2022 December 31, 2023, financing activities are primarily composed of the net proceeds ATM in June 2023 compared to $194.4 millions during for the year ended December 31, 2022 (that consisted of our global May 2022 ATM and June 2022 PIPE offering in the second quarter of 2022. 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 December 31, 2023, 149,793 222,988 shares and $0.3 million $0.2 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 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 atopy 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 Effective October 30, 2023 ,the Company and License agreement with Nestlé Health Science have been impacted signed an agreement, terminating the collaboration agreement between the two parties and the PII clinical study 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 which upfront and various other strategies milestones 1 to improve recruitment. As a result 3 are definitively acquired by DBV.

Consequently, as of the accumulation signing of recruitment delays, the Mutual Termination Letter Agreement and as of December 31 2023, we expect to incur additional clinical and production costs recorded the following :

- Loss on completion accrual reversal $19,9 millions;
- Deferred revenue accrual reversal $6.9 millions;
- Accrual for ongoing Clinical study completion $2.3 millions. This accrual represents our best estimate of the remainder expenses related to the Phase 2 ongoing 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 study which will be incurred after December 31, 2023 and until the end 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 study.

Clinical studies costs yet committed beyond December 31 2023 are 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.

settled by DBV. Our estimation of costs yet to be incurred and revenues yet to be recognized for the completion of the Phase 2 trial study contains uncertainties because as they require management to make assumptions and to apply judgment to estimate future cost and timeline for new patient enrollment in this PII. timelines to finish the study. These estimates are subjective and our ability to achieve current best estimates is may be affected by factors such factors. A $2.3 millions provision representing our current best estimates of costs yet to be incurred for the completion of the study was booked as ongoing COVID-19 pandemic and conflict in Ukraine. of December 31, 2023.

Share-Based Compensation

We have various several 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.

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:

	Assumptions per year ended December 31,		Assumptions per year ended December 31,	
Stock options per grant date	**2022**	**2021**	**2023**	**2022**
Weighted average shares price at grant date (in €)	2.33	5.71		
Weighted average shares price at grant date in €			2,08	2,33
Weighted average expected volatility	98.9%	90.2%	97,02%	98,90%
Weighted average risk-free interest rate	2.2%	(0.06)%	2,99%	2,20%
Weighted average expected term (in years)	6	6	6	6
Dividend yield	0	0	—	—
Weighted average fair value of stock-options (in €)	2.23	4.17		
Weighted average fair value of stock-options in €			1,33	2,23

* 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 $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 $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 $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 December 31, 2023, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the

effectiveness of our internal control over financial reporting. Under the supervision and with the participation of our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), management assessed the effectiveness of our internal control over financial reporting based upon the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are

subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

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 Rule13a-15(d)and15d-15(d)of the Exchange Act that occurred during the three months ended December 31, 2022 December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

During the fiscal quarter ended December 31, 2023, none of our officers or directors, as defined in Rule16a-1(f),adopted, modified or terminated a "Rule10b5-1trading arrangement" or a"non-Rule10b5-1trading arrangement," as those terms are defined in Item 408 of RegulationS-K.

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

Not applicable.

PART III

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

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in the sections titled "Board of Directors and Corporate Governance" 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

		Incorporated by Reference					Incorporated by Reference			
Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date	Description	Schedule/ Form	File Number	Exhibit	File Date
3.1*										
3.1*	By-laws (*statuts*) of the registrant (English translation)									
4.1	Form of Deposit Agreement	Form F-1/A	333-198870	4.1	10/15/14					
4.1						Form of Deposit Agreement	Form F-1/A	333-198870	4.1	10/15/14
4.2										

4.2	Form of American Depositary Receipt	Form F-1/A	333-198870	4.1	10/15/14	Form of American Depositary Receipt	Form F-1/A	333-198870	4.1	10/15/14
4.3	Description of Registered Securities	Form 20-F	001-36697	2.3	03/20/20					
4.3						Description of Registered Securities	Form 20-F	001-36697	2.3	03/20/20
4.4										
4.4	Registration Rights Agreement, dated as of March 23, 2018, between the registrant, 667, L.P. and Baker Brothers Life Sciences, L.P.	Form 6-K	001-36697	4.1	03/23/18	Registration Rights Agreement, dated as of March 23, 2018, between the registrant, 667, L.P. and Baker Brothers Life Sciences, L.P.	Form 6-K	001-36697	4.1	03/23/18
4.5	Registration Rights Agreement, dated as of June 8, 2022, between the registrant and the Investors named therein.	Form 8-K	001-36697	10.2	06/13/22					
4.5						Registration Rights Agreement, dated as of June 8, 2022, between the registrant and the Investors named therein.	Form 8-K	001-36697	10.2	06/13/22
4.6										
4.6	Securities Purchase Agreement, dated as of June 8, 2022, between the registrant and the Subscribers named therein.	Form 8-K	001-36697	10.1	06/13/22	Securities Purchase Agreement, dated as of June 8, 2022, between the registrant and the Subscribers named therein.	Form 8-K	001-36697	10.1	06/13/22

10.1	Office Lease between the registrant and GENERALI VIE, dated March 3, 2015 (English translation)	Form 20-F	001-36697	4.2	04/29/15					
10.1						Office Lease between the registrant and GENERALI VIE, dated March 3, 2025 (English translation)	Form 20-F	001-36697	4.2	04/29/15
10.2	Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hopitaux de Paris and Université Paris Descartes, dated January 7, 2009 (English translation)	Form F-1	333-198870	10.2	09/22/14					
10.2*										
10.2*										
10.3#	Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016	Form 20-F	001-36697	4.14	03/22/17					
10.3*										
10.3*										
10.4#	Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 2018	Form 20-F	001-36697	4.5	04/01/19					
10.4										

10.4						Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hopitaux de Paris and Université Paris Descartes, dated January 7, 2009 (English translation)	Form F-1	333-198870	10.2	09/22/14
10.5†	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1/A	333-198870	10.3	10/15/14					
10.5#										
10.5#						Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016	Form 20-F	001-36697	4.14	03/22/17
10.6†	2013 and 2014 Share Option Plans (English translation)	Form F-1	333-198870	10.4	09/22/14					
10.6#										
10.6#						Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 208	Form 20-F	001-36697	4.5	04/01/19
10.7†	2012, 2013 and 2014 Free Share Plans (English translation)	Form F-1	333-198870	10.5	09/22/14					
10.7*										
10.7*										

10.8†										
10.8†	Summary of BSA	Form F-1	333-198870	10.6	09/22/14	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1/A	333-198870	10.3	10/15/14
10.9†	Summary of BSPCE	Form F-1	333-198870	10.7	09/22/14					
10.10†	2015 Share Option Plan (English translation)	Form 20-F	001-36697	4.10	04/28/16					
10.11†	2015 Free Share Plans (English translation)	Form 20-F	001-36697	4.11	04/28/16					
10.9†						2013 and 2014 Share Option Plans (English translation)	Form F-1/A	333-198870	10.4	09/22/14

		Incorporated by Reference			
Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
10.12†	2016 Share Option Plan (English translation)	Form 20-F	001-36697	4.12	03/22/17
10.13†	2016 Free Share Plan (English translation)	Form 20-F	001-36697	4.13	03/22/17
10.14†	2017 Share Option Plan (English translation)	Form 20-F	001-36697	4.14	03/16/18
10.15†	2017 Free Share Plan (English translation)	Form 20-F	001-36697	4.15	03/16/18
10.16†	2018 Share Option Plan (English translation)	Form 20-F	001-36697	4.17	04/01/19
10.17†	2018 Free Share Plan (English translation)	Form 20-F	001-36697	4.18	04/01/19
10.18†	2019 Share Option Plan (English translation)	Form 20-F	001-36697	4.19	03/20/20
10.19†	2019 Free Share Plans (English translation)	Form 20-F	001-36697	4.20	03/20/20
10.20†	2020 Stock Option Plan (English translation)	Form 10-K	001-36697	10.21	03/17/21
10.21†	2020 Free Share Plan (English translation)	Form 10-K	001-36697	10.22	03/17/21
10.22†	2021 Stock Option Plan (English translation)	Form 10-K	001-36697	10.22	03/9/22
10.23†	2021 Free Share Plan (English translation)	Form 10-K	001-36697	10.23	03/9/22
10.24†*	2022 Stock Option Plan (English translation)				
10.25†*	2022 Free Share Plan (English translation)				
10.26†	Executive Agreement, dated November 29, 2018, between the registrant and Daniel Tassé	Form 10-K	001-36697	10.23	03/17/21
10.27†	First Amendment to the Executive Agreement of Daniel Tassé, dated June 27, 2019, between the registrant and Daniel Tassé	Form 10-K	001-36697	10.24	03/17/21
10.28†	Executive Agreement, dated July 22, 2019, between the registrant and Pharis Mohideen	Form 10-K	001-36697	10.25	03/17/21

10.29†	Letter Agreement, dated June 26, 2019, between the registrant and Sébastien Robitaille (English translation)	Form 10-K	001-36697	10.26	03/17/21
10.30†	Letter Agreement, dated December 1, 2020, between the registrant and Se´bastien Robitaille (English translation)	Form 10-K	001-36697	10.27	03/17/21
21.1	List of subsidiaries of the registrant	Form 20-F	001-36697	8.1	03/20/20
23.1*	Consent of Deloitte & Associés				
23.2*	Consent of KPMG S.A.				
24.1*	Power of Attorney (included on the signature page of this report).				
31.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				

		Incorporated by Reference			
Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
10.10†	2012, 2013 and 2014 Free Share Plans (English translation)	Form F-1/A	333-198870	10.5	09/22/14
10.11†	Summary of BSA	Form F-1	333-198870	10.6	09/22/14
10.12†	Summary of BSPCE	Form F-1	333-198870	10.7	09/22/14
10.13†	2015 Share Option Plan (English translation)	Form 20-F	001-36697	4.10	04/28/16
10.14†	2015 Free Share Plans (English translation)	Form 20-F	001-36697	4.11	04/28/16
10.15†	2016 Share Option Plan (English translation)	Form 20-F	001-36697	4.12	03/22/17
10.16†	2016 Free Share Plan (English translation)	Form 20-F	001-36697	4.13	03/22/17
10.17†	2017 Share Option Plan (English translation)	Form 20-F	001-36697	4.14	03/16/18
10.18†	2017 Free Share Plan (English translation)	Form 20-F	001-36697	4.15	03/16/18
10.19†	2018 Share Option Plan (English translation)	Form 20-F	001-36697	4.17	04/01/19
10.20†	2018 Free Share Plan (English translation)	Form 20-F	001-36697	4.18	04/01/19
10.21†	2019 Share Option Plan (English translation)	Form 20-F	001-36697	4.19	03/20/20
10.22†	2019 Free Share Plan (English translation)	Form 20-F	001-36697	4.20	03/20/20
10.23†	2020 Share Option Plan (English translation)	Form 10-K	001-36697	10.21	03/17/21
10.24†	2020 Free Share Plan (English translation)	Form 10-K	001-36697	10.22	03/17/21
10.25†	2021 Share Option Plan (English translation)	Form 10-K	001-36697	10.22	03/9/22
10.26†	2021 Free Share Plan (English translation)	Form 10-K	001-36697	10.23	03/9/22
10.27†	2022 Share Option Plan (English translation)	Form 10-K	001-36697	10.24	03/2/23
10.28†	2022 Free Share Plan (English translation)	Form 10-K	001-36697	10.25	03/2/23
10.29†	2023 Share Option Plan (English translation)	S-8	333-275662	99.3	11/20/23
10.30†	2023 Free Share Plan (English translation)	S-8	333-275662	99.2	11/20/23
10.31†	Executive Agreement, dated November 29, 2018, between the registration and Daniel Tassé	Form 10-K	001-36697	10.23	03/17/21
10.32†	First Amendment to the Executive Agreement of Daniel Tassé, dated June 27, 2019, between the registrant and Daniel Tassé	Form 10-K	001-36697	10.24	03/17/21
10.33†	Executive Agreement, dated July 22, 2019, between the registrant and Pharis Mohideen	Form 10-K	001-36697	10.25	03/17/21
10.34†	Letter Agreement, dated June 26, 2019, between the registrant and Sébastien Robitaille (English translation)	Form 10-K	001-36697	10.26	03/17/21

10.35†	Letter Agreement, dated December 1, 2020, between the registrant and Sébastien Robitaille (English translation)	Form 10-K	001-36697	10.27	03/17/21

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
10.36*†	English Summary Translation of Separation Agreement and Release between Sébastien Robitaille and registrant				
10.37*†	Letter Agreement, dated November 1, 2023, between the registrant and Virginie Boucinha (English translation)				
21.1*†	List of subsidiaries of the registrant				
23.1*	Consent of Deloitte & Associés				
23.2*	Consent of KPMG S.A.				
24.1**	Power of Attorney (included on the signature page of this report).				
31.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) 13a- 14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1**	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97.1*		Incentive Compensation Recoupment Policy, approved			
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 .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. 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 March 7, 2024

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities indicated on March 2, 2023 March 7, 2024.

Signature	Title
/s/ Daniel Tassé Daniel Tassé	Chief Executive Officer and Director (*Principal Executive Officer*)
/s/ Sebastién Robitaille Virginie Boucinha Sebastién Robitaille Virginie Boucinha	Chief Financial Officer (*Principal Financial and Accounting Officer*)
/s/ Michel de Rosen Michel de Rosen	Director
/s/ Mailys Ferrere Mailys Ferrere	Director
/s/ Michael J. Goller Michael J. Goller	Director
/s/ Danièle Guyot-Caparros Danièle Guyot-Caparros	Director
/s/ Timothy E. Morris Timothy E. Morris	Director

Signature	Title
/s/ Adora Ador Ndu Adora Ndu	Director
/s/ Julie O'Neill Julie O'Neill	Director
/s/ Ravi Madduri Rao Ravi Madduri Rao	Director
/s/ Daniel Soland Daniel Soland	Director

Index to Financial Statements

Annual Financial Statements for the Years Ended December 31, 2022 December 31, 2023 and 2021:2022:

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 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, cash flows and changes in shareholders' equity for each of the two years in the two-year period ended December 31, 2022 December 31, 2023, 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 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the two years in the two-year period ended December 31, 2022 December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash flows from operations since inception and current cash and cash equivalents are not sufficient for at least the next twelve months. These matters raise substantial doubt about the ability of the Company to continue as a going concern. Management's plans in regard to these matters are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

This matter is also described in the "Critical Audit Matter" section of our report.

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 Matter

The critical audit matters matter communicated below are matters is a matter arising from the current period audit of the consolidated financial statements that were was communicated or required to be communicated to the audit committee

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and that that: (1) relate relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of 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 matter below, providing a separate opinions opinion on the critical audit matters matter or on the accounts or disclosures to which they relate. it relates.

Pre-funded warrants— Going Concern – 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 1 to the consolidated financial statements

Critical Audit Matter Description

As described further in Notes 13 and 14 Note 1 to the consolidated financial statements, on May 31, 2016, the Company entered into an exclusive global collaboration agreement with Nestlé Health Science has incurred operating losses and negative cash flows from operations since inception. The Company does not generate product revenue and continues to develop MAG1C, a ready-to-use and standardized atopy patch test tool prepare for the diagnosis potential launch of cow's milk protein allergy its first product in infants the United States and toddlers. Under in the European Union, if approved. 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 of the exclusive collaboration, the Company is responsible for leading the development activities of MAG1C up through a pivotal Phase III clinical program. and conditions.

The Company's available cash and cash equivalents are not sufficient to support its operating plan for at least the next twelve months from the issuance date of these consolidated financial statements. As described in Note 1, such, substantial doubt exists regarding the

costs incurred Company's ability to continue 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. going concern.

We identified the evaluation of the costs Company's ability to be incurred continue as a going concern and estimated loss at completion for the collaboration agreement with Nestlé Health Science related disclosures as a critical audit matter. Given estimates are necessary This matter required a high degree of auditor judgment and increased effort when performing audit procedures to determine total costs to complete for each clinical phase evaluate (1) the reasonableness of management's forecasted operating expenses, and milestone (2) the adequacy of the collaboration agreement, auditing such estimates required complex audit judgment consolidated financial statements disclosure related to evaluate the estimated costs to achieve the performance obligations. going concern assessment.

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 evaluated the transaction prices design of the internal control related 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. Company's going concern assessment;
- We evaluated the estimate reasonableness of total the Company's forecasted operating expenses by inquiring of senior management to gain an understanding of the Company's operations, strategy, and research and development activities, compared the forecasted operating expenses to historical operating expenses and challenged expected costs, especially those costs that relate to be incurred by: future clinical trials;
    - 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.
    - We assessed management's ability to forecast operating expenses and cash flows by comparing prior year forecasts to actual financial results;

- 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.

- We assessed the adequacy of the consolidated financial statements' disclosure related to the going concern assessment by comparing it to the audit evidence obtained.

- 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

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

Paris-LaDéfense, France
March 7, 2024

KPMG S.A.
/s/ Cédric Adens

Partner

We have served as the Company's auditor since 2020.

Paris-LaDéfense, France

DBV Technologies S.A.

Consolidated Statements of Financial Position
(amounts in thousands, except share and per share data)

Assets	
Current assets:	
Cash and cash equivalents	
Trade receivables	
Other current assets	
Total current assets	
Property, plant, and equipment, net	
Right-of-useassets related to operating leases	
Intangible assets	
Othernon-currentassets	
Totalnon-currentassets	

Assets	
Current assets:	
Cash and cash equivalents	
Trade receivables	
Other current assets	

Total current assets
Property, plant, and equipment, net
Right-of-use assets related to operating leases
Intangible assets
Other non-current assets
Total non-current assets
Total Assets

Liabilities and shareholders' equity
Current liabilities Liabilities and shareholders' equity
Current liabilities
Trade payables
Short-term operating leases
Short-term financial debt
Current contingencies
Other current liabilities
Total current liabilities
Total current liabilities
Long-term operating leases
Long-term financial debt
Non-currentcontingencies
Othernon-currentliabilities
Totalnon-currentliabilities
Total liabilities
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, respectivel
Additionalpaid-incapital
Treasury stock, 149,793 and 153,631 ordinary shares as of December 31, 2022 and 2021, respectively, at cost Total liabi
Shareholders' equity:
Ordinary shares, €0.10 par value; 96,431,770 and 94,137,145shares authorized, and issued as at December 31, 2023 and 2022, respectively
Additional paid-in capital
Treasury stock, 222,988 and 149,793 ordinary shares as of December 31, 2023 and 2022, respectively, at cost
Accumulated deficit
Accumulated other comprehensive income
Accumulated currency translation effect
Accumulated other comprehensive income
Accumulated currency translation effect
Total shareholders' equity
Total liabilities and shareholders' equity

The accompanying notes are an integral part of these consolidated

DBV Technologies S.A.

Consolidated Statements of Operations and Comprehens
(amounts in thousands, except share and per share da

Operating income
Operating expenses
Research and development expenses
Sales & marketing expenses
General & administrative expenses
Restructuring reversal (expenses)
Total Operating expenses
Loss from operations
Financial income (expenses)

Loss before taxes	
Income tax	
Net loss	
Foreign currency translation differences, net of taxes	
Actuarial gains on employee benefits, net of taxes	
Total comprehensive loss	
Basic/diluted Net loss per share attributable to shareholders	
Weighted average number of shares outstanding used in computing per share amounts:	

	No
Operating income	
Operating expenses	
Research and development expenses	
Sales & marketing expenses	
General & administrative expenses	
Total Operating expenses	
Loss from operations	
Financial income (expenses)	
Loss before taxes	
Income tax	
Net loss	
Foreign currency translation differences, net of taxes	
Actuarial gains on employee benefits, net of taxes	
Total comprehensive loss	
Basic/diluted Net loss per share attributable to shareholders	
Weighted average number of shares outstanding used in computing per share amounts:	

The accompanying notes are an integral part of these consolidated fi

DBV Technologies S.A.

Consolidated Statements of Cash Flows

(amounts in thousands)

	Notes	Year ended December 31, 2022	2021
Net loss for the period		**$ (96,274)**	**$ (97,809)**
Adjustments to reconcile net loss to net cash used in operating activities:			
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
Changes in operating assets and liabilities:			
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 andnon-currentliabilities		152	(7,599)
Change in operating lease liabilities and right of use assets		(2,249)	(1,185)
Net cash flow used in operating activities		**(55,666)**	**(108,242)**
Cash flows used in investing activities:			
Acquisitions of property, plant, and equipment		(754)	(910)
Proceeds from property, plant, and equipment dispositions		8	604
Acquisitions of intangible assets		—	(8)
Acquisitions ofnon-currentfinancial assets		(123)	(119)
Proceeds fromnon-currentfinancial assets dispositions		770	—
Net cash flows used in investing activities		**(100)**	**(433)**

Cash flows provided by financing activities:			
(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)
Net cash flows provided by financing activities		**194,120**	**274**
Effect of exchange rate changes on cash and cash equivalents		(6,461)	(10,651)
Net (decrease) / increase in cash and cash equivalents		**131,893**	**(119,051)**
Net cash and cash equivalents at the beginning of the period		77,301	196,352
Net cash and cash equivalents at the end of the period	**3**	**$ 209,194**	**$ 77,301**

	Notes	Yea 2023
Net loss for the period		**$ (72,**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and accrued contingencies		(13,
Retirement pension obligations		
Expenses related to share-based payments		6,
Other elements		
Changes in operating assets and liabilities:		
Decrease (increase) in inventories and work in progress		
Decrease (increase) in trade receivables		
Decrease (increase) in other current assets		(3,
(Decrease) increase in trade payables		8,
(Decrease) increase in other current and non-current liabilities		(5,
Change in operating lease liabilities and right of use assets		1,
Net cash flow used in operating activities		**(79,**
Cash flows used in investing activities:		
Acquisitions of property, plant, and equipment		(
Proceeds from property, plant, and equipment dispositions		
Acquisitions of intangible assets		
Acquisitions of non-current financial assets		(
Proceeds from non-currentfinancial assets dispositions		
Net cash flows used in investing activities		**(**
Cash flows provided by financing activities:		
(Decrease) increase in conditional advances		
Treasury shares		(
Capital increases, net of transaction costs		6,
Other cash flows related to financing activities		
Net cash flows provided by financing activities		**6,**
Effect of exchange rate changes on cash and cash equivalents		5,
Net (decrease) / increase in cash and cash equivalents		**(67,**
Net cash and cash equivalents at the beginning of the period		209,
Net cash and cash equivalents at the end of the period	**3**	**$ 141,**

The accompanying notes are an integral part of these c

DBV Technologies S.A.

Consolidated Statements of Changes in Shareholders'
(amounts in thousands, except share and per share da

	Ordinary shares				
	Number of Shares Note 12	Amount	Additional paid-in capital	Treasury stock	Acc defic
Balance at January 1, 2021	**54,929,187**	**$ 6,518**	**$ 1,152,042**	**$ (1,169)**	**$ (958,**
Net (loss)					(97,
Other comprehensive (loss)					

Issuance of ordinary shares	166,575	20	496		
Issuance of share warrants	—	—	279	—	
Treasury shares				(63)	
Share-based payments (income) expenses			3,122		
Allocation of accumulated net losses	—	—	(797,823)	—	797,8
Balance at December 31, 2021	**55,095,762**	**$ 6,538**	**$ 358,115**	**$ (1,232)**	**$ (258,5**
Net (loss)					(96,2
Other comprehensive (loss)					
Issuance of ordinary shares	39,041,383	4,182	102,194		
Issuance of share warrants	—	—	88,094	—	
Treasury shares				123	
Share-based payments (income) expenses			5,026		
Allocation of accumulated net losses			(95,209)		95,2
Other change in equity	—	—	—	—	
Balance at December 31, 2022	**94,137,145**	**$ 10,720**	**$ 458,221**	**$ (1,109)**	**$ (259,5**

	Ordinary shares				
	Number of Shares Note 11	Amount	Additional paid-in capital	Treasury stock	Acc. deficit
Balance at December 31, 2021	**55,095,762**	**$ 6,538**	**$ 358,115**	**$ (1,232)**	**$ (258,528**
Net (loss)					(96,274
Other comprehensive (loss)					
Issuance of ordinary shares	39,041,383	4,182	102,194		
Issuance of share warrants	—	—	88,094	—	—
Treasury shares				123	
Share-based payments (income) expenses			5,026		
Allocation of accumulated net losses	—	—	(95,209)	—	95,209
Other change in equity	—	—	—	—	15
Balance at December 31, 2022	**94,137,145**	**$ 10,720**	**$ 458,221**	**$ (1,109)**	**$ (259,578**
Net (loss)					(72,726
Other comprehensive income (loss)					
Issuance of ordinary shares	2 294 625	252	6,670		
Issuance of share warrants	—	—	—	—	—
Treasury shares				(154)	
Share-based payments (income) expenses			6,019		
Allocation of accumulated net losses			(93,441)		93,441
Other change in equity	—	—	—	—	—
Balance at December 31, 2023	**96,431,770**	**$ 10,972**	**$ 377,468**	**$ (1,263)**	**$ (238,862**

The accompanying notes are an integral part of these consolidated fi

Notes to the Consolidated Financial Statements

Note 1: Nature of the business and principles and accounti

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 biopharmaceu Company’s therapeutic approach is based on epicutaneous immunotherapy, or EPIT™, a proprietary method of delivering biologica

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 tho 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 Accounti 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 cer the following notes.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidi

The following list presents all entities included in the consolidation scope for the years ended December 31, 2021 December 31, 2022 and 202

- • 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% own
- • 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

Functional Currency and Translation of Financial Statements in F

The Consolidated Financial Statements are presented in U.S. dollars, which differs from thefunctional currencyof the Company, being the Euro. The statements of financial position o 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 consol under the caption “Accumulated other comprehensive income (loss)” in the Consolidated State

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. A

exchange prevailing on that date. The resulting exchange gains or losses are recorded in the e “Financial income (expense)”; they will be recognized in profit or loss on disposal of the net inve

Use of estimates

The preparation of the Company’s consolidated financial statements requires the use of estima the reported amounts of assets, liabilities, and disclosures of contingent assets and liabilities at statements and the reported amount of income and expenses during the period. The Company historical experience and other factors that it believes to be reasonable under the circumstance

As of December 31, 2022, the ongoing pandemic may make management’s estimates vulnerab uncertainties were considered in the assumptions underlying the estimates and judgments use estimates have been and will continue to be affected by the ongoing pandemic. The Company an ongoing basis. The actual results may differ from these estimates.

On anon-goingbasis, management evaluates its estimates, primarily those related to: (1) evaluation of costs and measure of progress of the development wind-down activities con (3) assumptions used in the valuation ofright-of-useassets—operating lease, (4) impairment ofright-of-useassets related to leases and property, plant and equipment, (5) recovera determine the fair value and vesting conditions of share-based compensation plan, and (7) e

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 continue as a going concern exists.

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 as prepare for the potential launch of its first product in the United States and in the

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 C global restructuring plan in June 2020 to provide operational latitude to progress the clinical development and regulatory

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 C to generate the6-monthsafety and adhesion clinical data to assess a modified Viaskin Peanut patch and demonstrate the equivalence in alle

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

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 feedba intended patient population. The Company considers this approach as the most straightforward a

and improved in vivo adhesion of the modified Viaskin Peanut system. After receiving approval protocol for the new Phase 3 pivotal study of the modified Viaskin Peanut (“mVP”) patch was c has been prepared for FDA submission.

In May 2022, the Company established anAt-The-Market(“ATM”) program allowing to offer and who have expressed an interest, a total gross amount of up to $100 million $100 million of Ame Company’s intent is to use the net proceeds, if any, of sales of ADSs issued under the program equivalents, primarily for activities associated with potential approval and launch of Viaskin Pea development of the Company’s product candidates using its Viaskin Platform and for working c purposes.

In June 2022, the Company announced that its pivotal Phase 3 trial EPITOPE, assessing the s treatment of peanut-allergic toddlers ages 1 to 3 years, met its primary endpoint, with a statistic

Company also indicated continuing productive dialogue with the FDA on the protocol design of modified Viaskin Peanut patch in peanut-allergic peanut- allergic children ages 4 to 7 years.

During the same month, the Company announced private placement financing ("PIPE") amoun

In September 2022, after announcing initiating, the Company received a partial clinical hold lett clinical study. Within the FDA's communication, the modifications address design elements, inc minimum daily wear time and technical alignments in methods of categorizing data, to meet stu trial participants on active treatment.

In December 2022, the Company received confirmation from the FDA that it lifted the partial cli study. The Company indicated the updated protocol will be submitted to study sites for subsequ Committees approval.

The company has incurred operating losses and negative cash flows from operations since inc Company's available cash and cash equivalents are not projected to be sufficient to support its months. As such, there is substantial doubt regarding the Company's ability to continue as a go

Based on its our current operations, as well as our plans and assumptions, as revised pursuant EPITOPEPhase 3 study topline results and VITESSEPhase 3 partial clinical hold lift, as well as expects we expect that its our balance of cash and cash equivalents of $209.2 $141,4million as will be sufficient to fund its our operations for at least the next 12 months.until December 31,202

The Company intends to seek additional capital as it prepares for the launch of Viaskin Peanut, and development efforts. The Company will require substantial additional capital to fund its rese operating expenses. These capital requirements are expected to be funded through debt and e 2024. The Company may seek to finance its future cash needs through a combination of public collaborations, license and development agreements and other forms ofnon-dilutivefinancings.

The Company cannot guarantee that it will be able to obtain the necessary financing to meet its terms and conditions, including as a result of disruptions to the global financial markets due to pandemics, epidemics or global health crises and conflict in Ukraine. Ukraine or other global po ongoingCOVID-19pandemic and conflict in Ukraine have already caused extreme volatility and markets. A severe or prolonged economic downturn could result in a variety of risks to the Com additional capital when needed or on acceptable terms, if at all.

If the Company is not successful in its financing objectives, the Company could have to scale b 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 might otherwise seek to develop or commercialize independently.

These Consolidated Financial Statements do not include any adjustments to the carrying amou and reported expenses that may be necessary if the Company were unable to continue as a go

Intangible Assets

Acquired intangible assets are accounted for at acquisition cost less accumulated amortization. composed of software amortized on a straight-line basis over their estimated useful lives compr Intangible assets are reviewed for impairment whenever events or changes in circumstances in may not be recoverable. The costs related to the acquisition of licenses to software are posted 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 us improvements are amortized over the shorter of the estimated useful lives of the assets or the r

Depreciation is calculated on a straight-line basis over the assets' estimated useful lives as follo

PROPERTY, PLANT, AND EQUIPMENT ITEM	PERIOD
Laboratory equipment and technical facilities	
Building fixtures and leasehold improvements	
Office equipment and furniture	

Computer equipment

Impairment of assets

The Company periodically reviews long-lived assets for impairment whenever events or change carrying amount of an asset may not be recoverable or the estimated useful life is no longer ap and the recoverable value of the asset on an undiscounted cash flow basis is less than the carr 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 establish or control the use of, identified property, plant, or equipment for a period of time in exchange fo comprised of real estate leases, leases for industrial equipment and leases for office equipmen

The Company's real estate leases typically include options and features including rent free peri options and early termination options. The lease term is definedcontract-by-contractand corresp lease taking into account the optional periods that are reasonably certain to be exercised.

The Company recognizes operating lease liabilities based on the present value of the future mi at commencement date.

The Company does not recognize a lease liability or right of use asset for leases w

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 within Operating Expense in the Consolidated Statement of Operations. The operating lease cash flows are categorized under Net Cash Used in Operating A

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 deter incremental borrowing rates are determined using information on indicative borrowing rates that would be available to the Company based on the value, curre

Inventories and Work in Progress

Inventories are measured at the lower of cost or net realizable value at production costs calculated using thefirst-in,first-outmethod. It includes acquisition costs

Inventories are exclusively composed of work in progress relating to the production of the first batcl

During the launch phase of a new product, any inventories of that product are written dow

Financial Assets and Liabilities

Financial assets, excluding cash and cash equivalents, consist exclusively of other receivables. Other receivables arenon-derivativefinancial assets with a payment, which is fixed or 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 rep Statements of Operations and Comprehensive Loss

The Company also receives fromtime-to-timeassistance in the form of conditional advances, which are advances repayable in whole or in part based upon ack

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 app 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 resul statement for the fiscal year during which the modification is r

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

During the years ended December 31, 2022 December 31, 2023 and December 31, 2021 Dece any derivative financial instruments.

Fair Value Measurements

Fair value is defined as an exit price, representing the amount that would be received upon the liability in an orderly transaction between market participants. Fair value is a market-based mea assumptions that market participants would use in pricing an asset or liability. A three-tier fair va inputs in measuring fair value as follows:

- Level 1—Quoted market prices (unadjusted) in active markets for identical assets or liabi to access at the measurement date.
- Level 2—Quoted market prices for similar assets or liabilities in active markets, quoted pr liabilities in markets that are not active, or other inputs that are observable, either directly the use of models or other valuation methodologies.
- Level 3—Significant unobservable inputs for assets or liabilities that cannot be corroborat by the reporting entity's own assumptions utilizing the best information available and inclu activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon th to the fair value measurement. The Company's policy is to recognize transfers between levels event or change in circumstances that caused the transfer. There were no transfers into or out presented.

The Company considers its cash and cash equivalents, accounts receivable and accounts paya 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 short term remaining maturity at the date of purc Demand deposits therefore meet the definition of cash equivalents. Cash equivalents are measured at fair value using level 1 and any change

Concentration of Credit Risk

The Company has no significantoff-balancesheet risk, such as foreign currency contracts, options contracts, or other foreign hedging arrangements. Financial instruments that potenti 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 qual normal credit risk associated with commercial banking relationships or entities f

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

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 r become payable, with the Company's commitment being limited to c

The liability with respect to defined benefit plans is estimated using the follo

- 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 cost Service costs are recognized in profit or loss and are allocated

Actuarial gains and losses result from changes in actuarial assumptions and from differences between assumed and actual experience. Gains and losses recorded in other comprehe obligation for the defined benefit plan.

The Company's payments for the defined-contribution plans are recognized as expenses in the Consolidated Statements of Oper

Contingencies

An estimated loss from a loss contingency is recognized if the following tw

- 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 d
- 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 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 th

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 enc scientific research. Companies that prove that they have expenditures that meet the required cr against the payment of the income tax due for the fiscal year in which the expenditures were m applicable, can be reimbursed for the excess portion. The expenditures taken into account for t involve only research expenses.

In the fiscal year ended December 31, 2021, the Company recovered its Small andMedium-siz law, and became therefore eligible again for the immediate reimbursement of the Research Tax 31, 2022, the Company received the reimbursement of$
26.1million millions of the 2019, 2020 and 2021 fiscal year research tax credit. During the year e received the reimbursement of $5.9 millions of the 2022 fiscal year research tax credit.

Collaboration agreement with Nestlé Health Science

The Company entered into research and development collaboration agreements that may consist ofnon-r

Non-refundable
upfront payments are deferred and recognized as income over the period of th

Milestone payments represent amounts received depending upon the achievement of certain scientific, regulatory, or commercial milestones. They are recognized when the theco-contractingparty has no right to require refund of payment. The triggering event may be scientific results achieved by the Company or another party to

The Until the Termination letter agreement signed on October 30, 2023, the Company recognizes recognized income under thepercentage-of-completionmethod, using costs incurred incurred to date plus the estimate of margin at completion of the milestone. The Company periodically updates updated its measurement of progress and updates updated its cumulati to be recognized for the completion of the performance obligations. Please refer

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 inc consultants, costs of clinical trials, costs related to manufacturing clinical study materials, sponsored research, clinical trials insurance, other outside costs, depreciation, and facility vendors, or other payments made in advance of services performed or goods being delivered, as prepaid expenses, whic

Certain research and development projects are, or have been, partially funded by collaboration agreements, and the expenses related to the

related reimbursement of research and development costs under these agreements as income 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 iss (bons de souscription de parts de créateur d'entreprise or "BCEs"), stock options ("SO"), and re employees and/or executives. The company has also established established severalplans for "share warrants" (bons de souscription d'actions or "BSAs") granted tonon-employeemembers 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 subj personnel expenses (allocated by function in the Consolidated Statements of Operations and Comprehensive Loss) on a straight-line basis over the requisite service p

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 w accounting for the share-based share- based paymen

At each closing date, the Companyre-assessesthe number of options expected to vest. If applicable, the impacts of such revised estimates are recognized in the Conso

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 differen 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 operati 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 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, 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 be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is reco

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 e

Segment Information

The Company operates in a single operating segment: the conducting of research and develop products in order to market them in the future. The assets, liabilities, and operating losses reco

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

Net Loss Per Share

The Company calculates basic and diluted net loss per ordinary share by dividing the net loss by the weighted-average weighted- average number of ordinary shares outstanding 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 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 e subsequent events from the balance sheet date through March 2, 2023 March 7, 2024, the date at whi

Accounting Pronouncements adopted in 2022 202
The Company has not adopted any new accounting pronounceme

Accounting Pronouncements issued not yet adopt

In June 2016, the FASB Financial Accounting Standards Board (“FASB”) issued ASU2016-13—FinancialInstruments—Credit losses, which replaces the incurred loss impairment m consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The FASB has issued ASU2019-10which has resulted in the postponeme 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 impai its Consolidated Financial Statements. The Company does not expect that this new standard will did not have a

In October 2021, the FASB issued ASU2021-08,which amends ASC 805 to require acquiring entities to apply Topic 606 to recognize and measure contract assets and contract li December 15, 2022, including interim periods within those fiscal years. Adoption of this new standard ha

Accounting Pronouncements issued not yet adopt

Other accounting standards that have been issued or proposed by the FASBorother standards-setting bodies that do not require adoption until a future date are

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 Company submitted in October 2020 following the CRL. The FDA agreed with its position that a be considered as a new product entity provided the occlusion chamber of the current Viaskin P 250 µgmg (approximately 1/1,000 of one peanut) remains unchanged and performs in the sam to confirm the consistency of efficacy data between the existing and a modified patch, FDA req uptake of allergen (peanut protein) between the patches in peanut allergic children ages4-11. EQUAL, which stands for Equivalence in Uptake of Allergen. The FDA also recommended cond adhesion trial to assess a modified Viaskin Peanut patch in the intended patient population. Th STAMP, which stands for 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 the6-monthsafety and adhesion clinical data FDA requested via STAMP, which the Company expected to be the longest component of the mVP possible.
3. Demonstrate the equivalence in allergen uptake between the current and modified patches in the intended patient population via EQUAL. The complexity patch. To support those exchanges, the Company outlined its proposed approach to demonstrate allergen uptake equivalence between the two patches, a
   a. PREQUAL, a Phase1trial with adult healthy volunteers to optimize the allergen sample collection methodologies and validate the assays we ir
   b. 'EQUAL in adults'—a second Phase1 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 Phase1trial in healthy adult volunteers to evaluate the adhesion of five 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 mod circular patch for further development, which is approximately 50% larger in size relative to

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 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 all results from the allergen uptake studies might affect the design of th

After careful review of the FDA's information requests, in December 2021, the Company decide the development plans for Viaskin Peanut as requested by the FDA in the October 2021 feedba newly proposed sequential approach would require at least five rounds of exchanges that nece STAMP, the6-monthsafety and adhesion study. As such, in December 2021, the Company anno Phase3placebo-controlled efficacy trial for a modified Viaskin Peanut patch (mVP) in children ir Company considers this approach the most straightforward to potentially demonstrate effective of the modified Viaskin Peanut system. The FDA confirmed the Company's change in strategy exchanges.

In 2022, the Company announced the new Phase3pivotal study of the modified Viaskin Peanut old) and more sensitive children with peanut allergy.

On March 2, 2023, the Company announced the completion of EVOLVE, a 12-week caregiver a mVP patch in 50 peanut allergic children ages 4–11-years old. The objective of EVOLVE was to and ease of use for the mVP patch. The study concluded that the updated IFU supported corre lifting of the patch edges or detachment directly after application. Furthermore, EVOLVE conclu reported a positive ease of use experience with the mVP patch. In EVOLVE, DBV also tested th (eDiary) to collect information on activities of daily living and patch adhesion scores. EVOLVE v caregivers in VITESSE to capture the adhesion data in support of a potential BLA.

On March 7, 2023, the Company announced that the first patient was screened in the VITESSE anticipated by Q3 2024.

On April 19, 2023, the Company outlined the regulatory path for Viaskin Peanut in children 1-3 Company's Phase 3 EPITOPE study meets the pre-specified criteria for success for the primary efficacy study. The FDA requires additional safety data to augment the safety data collected fro safety study will also generate patch adhesion data and will include updated instructions for use

On July 31, 2023, the Company announced receipt of feedback from FDA on the two suppleme and COMFORT Toddlers. The COMFORT Toddlers safety study will enroll peanut allergic toddl efficacy results generated from the EPITOPE Phase 3 pivotal study. The COMFORT Children s children ages 4 – 7-years and will support the efficacy results anticipated from the ongoing VIT with a 6-month study duration and a 3:1 randomization (active:placebo) of approximately 400 s controlled COMFORT Toddlers study. The Company expects both COMFORT studies will asse measurements that were established in VITESSE.

Viaskin Peanut for children ages 4-11—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 part of the prescribed EMA review process. It is a letter that is meant to include any remaining process. The EMA indicated many of their objections and major objections from the Day 120 lis major objection remained at Day 180. The Major Objection questioned the limitations of the dat effect size supported by a single pivotal study.

On December 20, 2021, the Company announced it has withdrawn withdrew the MAA for Viask our decision. The initial filing was supported by data from a single, placebo-controlled Phase3

pivotal trial known as PEPITES(V712-301).The decision to withdraw was based on the view of a single pivotal clinical trial were not sufficient to preclude a Major Objection at Day 180 in the r from a second Viaskin Peanut pivotal clinical trial will support a more robust path for licensure o intend to resubmit the MAA when that data set is available.

Viaskin Peanut for Children ages1-3

In June 2020, the Company announced that in Part A, patients in both treatment arms showed
of therapy, as assessed by a double-blind placebo- controlled food challenge and biomarker re
Part B and the efficacy analyses from Part A were not statistically powered to demonstrate sup
These results validate the ongoing investigation of the 250 µg dose in this age group, which is
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 3
and 118 were in the active and placebo arms, respectively. Enrollment was balanced for age a
the active and placebo treatment arms.

The Company intends to further analyze the data from EPITOPE and explore regulatory pathwa
3 years, given the high unmet need and absence of approved treatments for this vulnerable po

On April 19, 2023, the Company announced it will begin a new safety study after it received co
study meets the pre-specified criteria for success for the primary endpoint, with no additional ef
will increase the safety data collected from EPITOPE in support of a BLA. It will also generate
updated instructions for use.

On May 10, 2023, the New England Journal of Medicine (NEJM) published results that demons
with VP was statistically superior to placebo in desensitizing children to peanut exposure by inc
allergic symptoms. As stated in an accompanying editorial piece, these data are seen as “very
as there are currently no approved treatment options for peanut-allergic children under the age
Company confirmed it is advancing regulatory efforts for VP in toddlers ages 1-3 years old with

In November 2023, the Company announced the interim analyses from the first year of the ope
were presented at the annual American College of Allergy, Asthma and Immunology (ACAAI) i

Viaskin Peanut for Children ages4-7

On September 7, 2022, we announced the initiation of VITESSE, a new Phase3pivotal study o
in children ages4-7years with peanut allergy. We defined initiation as the submission of the trial
subsequent Institutional Review Board (IRB)/ approval and Ethics Committee (EC) approval.

opinion.

On September 21, 2022, we announced we had received feedback from the FDA in the form o
partial clinical hold letter, the FDA specified changes to elements of the VITESSE protocol, ack
a future BLA submission. In the following months, we engaged with the FDA to address the fee
letter and to finalize the VITESSE protocol. In addition, we continued internal preparations for V
assessment andstart-upactivities for prompt study launch once the partial clinical hold was lifte

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

On March 7, 2023, the Company announced screening of the first patient in VITESSE. Screeni
2024.

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

In 2024, we plan to initiate a six-monthsupplemental safety study (COMFORT Children) in pear
additional safety datagenerated by thisstudy will supplement the safety data generated by the V
comprised of approximately600 children ages 4 to 7 years treated with Viaskin Peanut. This stu
REALISE (REAL Life Use and Safety of EPIT) safety study that we previously conducted with V
years.

Diagnostic Tool Development

On October 30, 2023, the Company and NESTEC entered into a Mutual Termination Letter Agr
Agreement. Each party remains responsible for its own costs and expenses related to its respe
licenses and sublicenses, granted by either party to the other party under the Collaboration Agr
licenses to intellectual property, were revoked and terminated.

Consequently, since signing the Mutual Termination Letter Agreement and as of December 31,

- Loss on completion accrual reversal $19,9 millions (Other Operating Income);
- Deferred revenue accrual reversal $6.9 millions (Operating Expenses);
- Accrual for ongoing Clinical study completion $2.3 millions (Operating Expenses). This accru
  remainder expenses related to the ongoing clinical study which will be incurred after Decem

Financing

In May 2022, the Company announced that pursuant to the Company'sAt-The-Marketprogram (Program"), it had issued and completed sales of new ordinary shares (the "Ordinary Shares") ir ("ADSs"), for a total gross amount of $15.3millions($14.1million ($14.1 millions million net of tra ,6,036,238new Ordinary Shares in form of ADS have been issued through a capital increase wi shareholders reserved to specific categories of persons fulfilling certain characteristics (the "AT of1.27dollar per ADS (i.e., a subscription price per Ordinary Share of2.41euro based on the US for1euro, as published by the European Central Bank on May 4,2022)May 4, 2022) and each A ofoneordinary share of the Company.

Pursuant to the ATM program, the Company issued and completed sales of new Ordinary Shar amount of $7.8 millions on June 14, 2023 (and a net amount of $6.9 millions after $0.9 capital i

In June 2022, the Company announced an aggregate $194 million $194 million ($180.4 million in public equity (PIPE) financing (corresponding to €181 million on the basis of an exchange rat European Central Bank on June 8, 2022) from the sale of 32,855,669 ordinary shares, as well a 28,276,331 ordinary shares. shares (the "June2022

PIPE").The ordinary shares were sold to the purchasers at a price per ordinary share of €3.00 (thepre-fundedwarrants were sold to the purchasers at apre-fundedprice of €2.90 (correspondin equals the per share price for the ordinary shares less the remaining €0.10 exercise price for ea proceeds from theJune 2022 PIPE financing total approximately $194 million (correspondingmi €181millions), before deducting private placement expenses.

The ordinary shares issued in the June 2022 PIPE, including the ordinary shares issuable upor the PIPE financing, have not werenot been registered under the Securities Act of 1933, as ame not be offered or sold in the United States except pursuant to an effective registration statemen registration requirements. In connection with the PIPE financing, the Company entered into a re "Registration Rights Agreement"), pursuant to which the Company has filed a registration state Commission (the "SEC") registering the resal resale ofe of 59,269,629ordinary shares issued in ordinary shares underlying thepre-fundedwarrants.*warrants.*

COVID-19Pandemic

On March 11, 2020, the World Health Organization declaredCOVID-19a pandemic. During the experienced a decrease in new patients enrolling in the ongoing clinical studies and had to ada patients were subject to travel restrictions and other containment measures.

The Company has continued to assess the impact of the COVID-19 pandemic and uncertaintie and the conduct of our clinical. As of December 31, 2022, those uncertainties were taken into a estimates and judgments used by the Company. The Company continues to update these estin evolves. The effects of the

COVID-19pandemic are presented in the relevant line items of the Consolidated Statement of F Statement of Operations and Comprehensive Loss according to the function or nature of the in

Legal Proceedings

From time to time, we may become subject to various legal proceedings and claims that arise i 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 th TravisIto-Stonev. DBV Technologies, et al., Case No.2:19-cv-00525.The complaint, as amende Chief Executive Officer, its current Chief Executive Officer, its former Deputy Chief Executive O violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Excha thereunder. The plaintiffs seek unspecified damages on behalf of a purported class of persons between February 14, 2018 and August 4, 2020 and also held the Company's securities on De 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 wh Company's Motion to Dismiss the Second Amended Class Action Complaint without prejudice. Plaintiffs replead their case by filing a Third Amended Class Action Complaint on September 3(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 Pl
prejudice. The Court indicated that the Third Amended Complaint was deficient in a number of
Securities Exchange Act of 1934, and ordered the matter closed. Per court procedural rules, th
dismissal of the Third Amended Complaint. This Plaintiffs failed to file an appeal of the dismiss
the30-dayperiod 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 equival

	De
	2022
Cash	30,1
Cash equivalents	179,0
Total cash and cash equivalentsas reported in statement of financial position	**209,1**
Bank overdrafts	–
Total net cash and cash equivalents as reported in the statement of cash flow	**209,1**

	D
	2023
Cash	10,5
Cash equivalents	130,8
Total cash and cash equivalents as reported in statement of financial position	**141,3**
Bank overdrafts	–
Total net cash and cash equivalents as reported in the statement of cash flow	**141,3**

Cash equivalents are immediately convertible into cash at no or insignificant cost on demand. T
measurements.

Note 4 Other Current Assets

Other current assets consisted of the following:

Research tax credit	
Other tax claims	
Prepaid expenses	
Other receivables	
Total	

Research tax credit	
Other tax claims	
Prepaid expenses	
Other receivables	
Total	

The other tax claims are primarily related to deductible VAT. Prepaid expenses are comprised p
legal and scientific consulting fees. Prepaid expenses also include upfront payments which are
clinical studies.

Research tax credit

In the fiscal year ended December 31, 2021, the Company recovered its Small andMedium-siz
law, and became therefore eligible again for the immediate reimbursement of the Research Tax

Duringthe year ended December 31, 2022, the Company received the reimbursement of$26.12
2021 fiscal year research tax credit.

During the year ended December 31, 2023, the Company :

- received the reimbursement of $5.9 millions of the 2022 fiscal year research tax credit ;
- made a complementary statement for 2020, 2021 and 2022 fiscal year research tax credit. A been booked for $2.9 millions.

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

Opening balance sheet receivable as of January 1, 2021	
+ 2021 fiscal year research tax credit	
- Payment received	
- Adjustment and currency translation effect	
Closing balance sheet receivable as of December 31, 2021	
Ofwhich—Non-currentportion	
Of which—Current portion	

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Opening balance sheet receivable as of January 1, 2022	
+ 2022 fiscal year research tax credit	
- Payment received	
- Adjustment and currency translation effect	
Closing balance sheet receivable as of December 31, 2022	
Ofwhich—Non-currentportion	
Of which—Current portion	

Opening balance sheet receivable as of January 1, 2023	
+ 2023 fiscal year research tax credit (1)	
- Payment received	
- Adjustment and currency translation effect	
Closing balance sheet receivable as of December 31, 2023	
Of which—Non-current portion	
Of which—Current portion	

(1) Included 2020, 2021 and 2022 complementary research tax credit made during the fiscal

Note 5 Property, Plant, and Equipment

Property and equipment, net consisted of the following: following:

	1/1/2022	Currency translation effect	Increase	Decrease	
Laboratory equipment	21,434	(1,246)	—	—	
Building fixtures	3,958	(196)	55	(604)	
Office equipment	864	(25)	74	(428)	
Computer equipment	1,299	(65)	16	—	
Property, plant, and equipment in progress	4,390	(252)	608	—	
Total, gross	**31,945**	**(1,783)**	**754**	**(1,032)**	
Less accumulated amort. and deprec.	(13,799)	703	(2,723)	1,031	
Total, net	**18,146**	**(1,080)**	**(1,968)**	**(1)**	

	1/1/2021	Currency translation effect	Increase	Decrease	12/31/2021	1/1/2023
Laboratory equipment	23,072	(1,783)	853	(708)	21,434	20,459
Building fixtures	7,767	(408)	48	(3,449)	3,958	3,214
Office equipment	970	(39)	—	(67)	864	485
Computer equipment	1,846	(92)	9	(464)	1,299	1,258
Property, plant, and equipment in progress	7,828	(477)		(2,960)	4,390	4,468
Total, gross	**41,482**	**(2,799)**	**910**	**(7,648)**	**31,945**	**29,884**
Less accumulated amortization and depreciation	(16,690)	1,109	(4,437)	6,219	(13,799)	(14,788
Total, net	**24,792**	**(1,690)**	**(3,527)**	**(1,429)**	**18,146**	**15,096**

	1/1/2022	Currency translation effect	Increas
Laboratory equipment	21,434	(1,246)	—
Building fixtures	3,958	(196)	5
Office equipment	864	(25)	7
Computer equipment	1,299	(65)	1
Property, plant, and equipment in progress	4,390	(252)	60
Total, gross	**31,945**	**(1,783)**	**75**
Less accumulated amortization and depreciation	(13,799)	703	(2,72
Total, net	**18,146**	**(1,080)**	**(1,96**

The depreciation and amortization expense for each of the years ended December 31, 2022 De $2.7 million $3.6 million and $4.4 million $2.7 millionrespectively.

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 Dec 2021, 2022, are as follows:

	December 31, 2022	
	Real estate	Other assets
Current portion	1,972	79
Year 2	1,168	74
Year 3	65	6
Year 4	—	—
Year 5	—	—
Thereafter	—	—
Total minimum lease payments	**3,204**	**160**
Less: Effects of discounting	(325)	(17)
Present value of operating lease	**2,879**	**143**
Less: current portion	(1,823)	(71)
Long-term operating lease	**1,055**	**72**

Weighted average remaining lease term (years)	1.40	—
Weighted average discount rate	3.00%	2.45%

	December 31, 202	
	Real estate	Other assets
Current portion	1,205	71
Year 2	65	11
Year 3	421	—
Year 4	919	—
Year 5	919	—
Thereafter	3,677	—
Total minimum lease payments	**7,205**	**81**
Less: Effects of discounting	(1,617)	(9)
Present value of operating lease	**5,588**	**73**
Less: current portion	(1,072)	(68)
Long-term operating lease	**4,516**	**5**
Weighted average remaining lease term (years)	7.954	—
Weighted average discount rate	4.53%	2.50%

The Company recognizes rent expense, calculated as the remaining cost of the lease allocated straight-line basis. Rent expense presented in the consolidated statement of operations and co

	December 31,
	2022
Operating lease expense	1,800
Refurbishing impact	
Net termination impact	(1,657)

InJanuary 2022, the company entered into a termination agreement for its U.S. office in Summi use. The Company recognized an income of $1.2 million $1.2 million as of June 30, 2022 due t lease, offset by the payment of aone-timelump sum early termination fee of $1.5 million. $1.5 m

On March 28, 2022, the Company entered into a binding office lease agreement in New Jersey months. months. The lease commencement was based upon delivery of possession of the pren 1, 2022. Right of use and related lease debt have been recorded starting April 1, 2022 for a gro

In November, 2023, the Company signed agreements for the new headquarters in Chatillon, Fr
- a short term lease agreement in order to fit the new offices,
- A lease agreement starting on April 16, 2024

The lease commencement was based upon delivery of possession of the premises by the Land Right of use and related lease debt have been recorded starting November, 2023 for a gross ar

Supplementalcash flow information related to operating leases is as follows for the period Dece 2023 and 2021: 2022:

Cash paid for amounts included in the measurement of lease liabilities
Operating cash flows from operating leases

Cash paid for amounts included in the measurement of lease liabilities
Operating cash flows from operating leases

Note 7 Othernon-currentassets

Othernon-currentassets consisted of the following:

FX facility collateral account	
Deposits, pledged securities and othernon-currentfinancial assets	
Liquidity contract	
Total othernon-currentassets	

FX facility collateral account	
Deposits, pledged securities and other non-current financial assets	
Liquidity contract	
Total other non-current assets	

The othernon-currentassets are composed of security deposits paid to premises lessors, pledg
collateral account to guarantee a FX facility not used as of December 31, 2022 December 31, 2

Under the liquidity contract, 149,793 222,988 treasury shares were allocated as a reduction of $
2022 December 31, 2023 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 pre
at the end of each fiscal yearpresented.

Other Current Liabilities

Other current liabilities consisted of the following:

Social debt	
Deferred income	
Tax liabilities	
Other debts	
Total	

Social debt	
Deferred income	
Tax liabilities	
Other debts	
Total	

The other current liabilities include short-term debt related to employees' bonus accruals, as we

On October 30, 2023, the Company signedaTermination letter agreement withDeferred income
collaboration agreement with Nestlé Health Science, which amounted to $2.1 million as of Dec

As of December 312023, we recordeda deferred revenue accrual reversal of $6.9millions (inclu
$4.7 millions in non current liabilities).

Note 9 Financial debt Other Current and OtherNon-CurrentLiabilities

Financial debt—Conditional Advances

The table below presents the details of the debts recorded on the statement of financial positio

Balance sheet debt at start of period 01/01/2021	

Repayments

Other movements

Balance sheet debt as at 12/31/2021

Ofwhich—Non-currentportion

Of which—Current portion

Stated interest rate

Discount rate

Maturity (in years)

Balance sheet debt at start of period 01/01/2022

Repayments

Other movements

Balance sheet debt as at 12/31/2022

Stated interest rate

Discount rate

Maturity (in years)

The changes appearing in “Other movements” are comprised of the effect of discounting condit

BpiFrance Financement Interest Free Loan

The Company has been granted until September 2022 a €3.0 million interest-free Innovation lo financing the pharmaceutical development of Viaskin™Milk. This amount was received in a sing

Due dates of liabilities

The following table shows the maturity of the Company’s liabilities (except leases disclos

	Carrying	2023	2024	Thereafter
Other liabilities	13,945	9,210	4,735	—
Supplier accounts payable and related payables	14,473	14,473	—	—
Total liabilities	**28,418**	**23,683**	**4,735**	**—**

	Total	2024	2025	Thereafter
Other current liabilities	8,934	8,934	—	—
Supplier accounts payable and related payables	23,302	23,302	—	—
Total liabilities	**32,236**	**32,236**	**—**	**—**

As detailed in Note 8, the The current portion of other liabilities mainly inc

Othernon-currentliabilities

Effective October 30, 2023 ,the Company and deferred incomes from Nestlé Health Science signed an agreement, terminating the collaboratio

Consequently as of December 31, 2023, we recorded the fo

- Deferred revenue accrual reversal $6.9 millions (including $4.7 millions recorded in Othernon-currentliabilities as of December 31, 2022).

Note 10 Fair value measurement

The Company reports assets and liabilities recorded at fair value on the Company’s consolidated balance sheets based upon th

The fair value measurement level within the fair value hierarchy for a particular asset or liability that is significant to the fair value measurement. Valuation techniques maximize the use of obs unobservable inputs.

Financial instruments not measured at fair value on the Company’s consolidated statement of f disclosure of their fair values include cash and cash equivalents, accounts receivable, deposits conditional advances. The fair values of these financial instruments are deemed to approximate

The fair values of cash and cash equivalents, accounts receivable, deposits, liquidity contract a Level 1. The fair value of conditional advance was categorized as Level 2 and was estimated b using the effective interest rate. For the interest-free conditional advances, the discount rate ap treasury bonds over the time period that corresponds to the time period of the repayment of the

There has been no transfer between levels of the fair value hierarchy during the years ended D
2022. 2023.

Note 11 Share Capital Issued

The share capital, as of December 31, 2022 December 31, 2023, is set at the sum of €9,413,71
converted at historical rates). It is divided into 94,137,145 96,431,770 fully authorized, subscrib
of €0.10. €0.10.

Thisnumber does not reflect ordinary shares issuable upon exercise or settlement ofnon-emplo
and restricted stock units ("RSU") granted to both employees andnon-employeesof the Compa

All the shares give their owners the right to a proportional share of the income and the net asse

Pursuant to the authorization granted by the SH General Meeting, the Board of Directors, at its
General Meeting"):

- decided, within the framework of theJune 2022 PIPE financing the principle of a capital in
  preferential subscription rights, reserved for categories of persons meeting the characteri
  thresolution of the Board General Meeting, through the issuance of Ordinary Shares and war
  a maximum amount of 6,113,200 New Ordinary Shares, corresponding to the maximum issu
  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 thesub-delegationsof authority granted by the B
8, 2022, after receiving the favorable opinion of the Pricing Committee established by the Boar

- decided, making use of the 18thresolution of the Board General Meeting, to proceed with
  of preferential subscription rights reserved for categories of investors, in accordance with
  Code, an amount of € 3,285,566.90, through the issuance of (i) 32,855,669 New Ordinary
  price of €2.90 of share premium) and to be fully paid up at the time of subscription, i.e. a

capital increase of a nominal amount of €3,285,566.90 together with a share premium of € 95,2

- decided to set the maximum nominal amount of the capital increase resulting from the fu
  securities giving access to the capital issued or to be issued, in accordance with the lega
- determined the list of beneficiaries (designated within each of the categories of persons

The Company has assessed thepre-fundedwarrants for appropriate equity or liability classificat

The table below presents the changes in the share capital of the Company as of December 31

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

Date	Nature of the transactions
Balance as of December 31, 2020	
02/22/2021	Capital increase by employee warrants
05/12/2021	Capital increase by employee warrants
05/17/2021	Capital increase by employee warrants
05/18/2021	Capital increase by employee warrants
05/19/2021	Retained earnings charged on share premiu
05/21/2021	Capital increase by employee warrants
05/26/2021	Capital increase by employee warrants
05/28/2021	Capital increase by employee warrants
06/10/2021	Issuance of share warrants
10/07/2021	Capital increase by ordinary shares
11/24/2021	Capital increase by ordinary shares
12/20/2021	Capital increase by ordinary shares
12/31/2021	Share-based payments
Balance as of December 31, 2021	
03/23/2022	Capital increase by ordinary shares
05/10/2022	Capital increase by ATM program
05/12/2022	Retained earnings charged on share premiu
05/19/2022	Capital increase by employee warrants
05/24/2022	Capital increase by employee warrants
06/09/2022	Capital increase by ordinary shares
06/09/2022	Capital increase by share warrants
06/10/2022	Capital increase by employee warrants
07/08/2022	Capital increase by employee warrants
09/23/2022	Capital increase by ordinary shares
11/19/2022	Capital increase by ordinary shares
11/22/2022	Capital increase by ordinary shares
11/24/2022	Capital increase by ordinary shares
12/31/2021	Share-based payments
Balance as of December 31, 2022	

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

Date	Nature of the tran
Balance as of December 31, 2021	
03/23/2022	Capital increase by ordinary shares
05/10/2022	Capital increase by ATM program
05/12/2022	Retained earnings charged on share premium
05/19/2022	Capital increase by employee warrants
05/24/2022	Capital increase by employee warrants
06/09/2022	Capital increase by ordinary shares
06/09/2022	Capital increase by share warrants
06/10/2022	Capital increase by employee warrants
07/08/2022	Capital increase by employee warrants
09/23/2022	Capital increase by ordinary shares
11/19/2022	Capital increase by ordinary shares
11/22/2022	Capital increase by ordinary shares
11/24/2022	Capital increase by ordinary shares
12/31/2021	Share-based payments
Balance as of December 31, 2022	
03/23/2023	Capital increase by employee warrants
04/12/2023	Retained earnings charged on share premium

05/19/2023	Capital increase by ordinary shares
05/22/2023	Capital increase by ordinary shares
05/24/2023	Capital increase by ordinary shares
06/16/2023	Capital increase by ATM program
09/23/2023	Capital increase by ordinary shares
10/25/2023	Capital increase by ordinary shares
11/19/2023	Capital increase by ordinary shares
11/21/2023	Capital increase by ordinary shares
11/22/2023	Capital increase by ordinary shares . . . . .
11/24/2023	Capital increase by ordinary shares . . . . .
12/31/2023	Share-based payments
Balance as of December 31, 2023.	

In May 2022, April 2023, pursuant to the authorization granted by

The different stock options plans granted by the Board of Directors are similar in their nature a

All SO issued havea ten-year contractuallife. SO are expensed in accordance with the followin

- • Before June 22, 2018 and after from January 15, 2020 to November 22, 2021, SO grante

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Short-term benefits	
Post-employment benefits	
Termination benefits	
Share-based payments	
Total	

Short-term benefits	
Post-employment benefits	
Termination benefits	
Share-based payments	
Total	

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