

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____ to _____

Commission file number 001-36697

DBV TECHNOLOGIES S.A.

(Exact name of registrant as specified in its charter)

France
State or other jurisdiction of
incorporation or organization
177-181 avenue Pierre Brossolette
Montrouge France
(Address of principal executive offices)

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

92120
(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing one-half of one ordinary share, nominal value €0.10 per share	DBVT	The Nasdaq Stock Market LLC
Ordinary shares, nominal value €0.10 per share*	n/a	The Nasdaq Stock Market LLC

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer
Non-accelerated filer

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing price per American Depositary Share, or ADS, of the registrant's ADSs on The Nasdaq Global Select Market on June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter) was \$343.3 million.

As of March 15, 2020, the registrant had 54,936,687 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 2021 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, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS.

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

- statements regarding the impact of the ongoing COVID-19 pandemic and its effects on our operations, research and development and clinical trials 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 for Viaskin™ Peanut to the U.S. Food and Drug Administration;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- the sufficiency of existing capital resources;
- the implementation of our global restructuring plan, 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 grant 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.
- COVID-19 could impact our business.
- We are limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations.
- We are obligated to develop and maintain a system of effective internal controls over financial reporting. These internal controls may be determined to be not effective, which may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares and ADSs.
- 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.
- We depend almost entirely on the successful development of our novel Viaskin technology. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Viaskin products.
- Our product candidates have undergone and/or will be required to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we, or our collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.
- In our clinical trials, we utilize an oral food challenge procedure intentionally designed to trigger an allergic reaction, which could be severe or life-threatening.
- Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay or prevent our ability to generate revenues.
- If our product candidates are not approved by the FDA, we will be unable to commercialize them in the United States.
- 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 marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.
- Even if we, or our collaborators, obtain marketing 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 marketing approval in the future could be subject to postmarketing 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.

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- 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.
 - Our Viaskin product candidates may not be able to be manufactured profitably on a large enough scale to support commercialization.
 - 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.
 - 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 marketing approval, if any.
 - Changes in regulatory requirements, FDA guidance or guidance from certain European regulatory authorities or unanticipated events during our clinical trials of Viaskin patch products may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us and could delay our development timeline.
 - If we do not secure collaborations with strategic partners to test, commercialize and manufacture certain product candidates outside of food allergies, we may not be able to successfully develop products and generate meaningful revenues.
 - Our ability to compete may decline if we do not adequately protect our proprietary rights.
 - Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.
 - We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.
 - We are in the process of implementing a global restructuring program, and we may not be able to realize the anticipated benefits of this program or any other efforts to preserve operational flexibility and financial resources.
 - 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.
 - We may incur significant costs from class action litigation.

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- 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 implement sales, marketing and distribution capabilities before we are able to bring any product candidate to market, and as a result, we may encounter difficulties in managing this development and expansion, which could disrupt our operations.
 - If we are not able to comply with the applicable continued listing requirements or standards of 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.
 - Our by-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.
 - U.S. Investors may have difficulty enforcing civil liabilities against our company and directors and senior management.
 - U.S. holders of our ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

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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. “ViaskinTM”, “EPITTM” 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 prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

Item 1. Business.

Overview

DBV Technologies is a clinical-stage biopharmaceutical company dedicated to developing and commercializing safe, effective, and convenient therapies for patients with food allergies and other immunological conditions.

Our therapeutic approach is based on epicutaneous immunotherapy, or EPIT™, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin, an epicutaneous patch (i.e., a skin patch). We have generated significant data demonstrating that the mechanism of action of Viaskin is novel and differentiated, as it targets specific antigen-presenting immune cells in the skin called Langerhans cells. Langerhans cells capture the antigen and migrate to the lymph node to activate the immune system without allowing passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to address areas of unmet medical need, including food allergies. Safety is paramount to children with food allergies and their families because the introduction of the offending allergen into an allergic child's bloodstream can cause severe and life-threatening allergic reactions, such as anaphylactic shock. We believe Viaskin may offer a convenient, self-administered, non-invasive immunotherapy to patients.

Our most advanced product candidate is Viaskin Peanut, which has been evaluated in nine clinical studies, including four Phase II studies and two Phase III studies, as a potential therapy for children ages four to eleven with peanut allergy. We also have an ongoing Phase III study of Viaskin Peanut in children ages one to three with peanut allergy.

We have two earlier-stage food allergy programs: Viaskin Milk, which is in Phase II of clinical development, and Viaskin Egg, which is in preclinical development. We are also exploring potential applications of our Viaskin platform in vaccines and other immune diseases such as 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:

- **Seek marketing approval for Viaskin Peanut in the European Union.** The European Medicines Agency, or EMA, validated our Marketing Authorization Application, or MAA, for Viaskin™ Peanut in November 2020. The validation 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 eleven years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, began their review of the application and will provide a recommendation to the European Commission, or EC, on whether to grant a marketing authorization once their review is complete.
- **Seek marketing approval for Viaskin Peanut in the United States.** On August 3, 2020, we received a Complete Response Letter, or CRL, from the U.S. Food and Drug Administration, or FDA, regarding our Biologics License Application, or BLA, for Viaskin Peanut in children ages four to eleven. The FDA indicated it could not approve the Viaskin Peanut BLA in its current form and identified concerns regarding the impact of patch-site adhesion on efficacy. The FDA indicated the need for patch modifications, and subsequently a new human factor study and supplementary clinical data to support a 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. On January 13, 2021, we received written responses from the FDA to questions we submitted in October 2020 following the CRL. We believe the FDA feedback provides a well-defined regulatory path forward, and we are working to advance our BLA re-submission plan based on the FDA guidance.

- **Pursue the continued development of Viaskin Peanut for toddlers ages one to three.** In August 2017, we initiated the EPIT in Toddlers with Peanut Allergy, or EPITOPE, trial, a Phase III clinical trial assessing the safety and efficacy of Viaskin™ Peanut for the treatment of peanut allergic patients one to three years of age. In September 2018, we announced that the independent Data Safety Monitoring Board, or DSMB, completed its planned safety review of Part A of the EPITOPE trial, involving two doses (100 µg and 250 µg). The DSMB did not identify any safety concerns for patients enrolled in Part A of the trial and recommended that the trial continue as planned with the 250 µg dose selected for investigation in Part B. We expect Part B to be fully enrolled by the end of the first quarter of 2021.
- **Commercialize our Viaskin product candidates in the United States and other major markets.** Our team has broad expertise in food allergies, how they are treated and their market dynamics. Given our team's knowledge in food allergies, and the limited number and targeted nature of food allergy healthcare providers in our target markets, we currently intend to launch and commercialize our food allergies product candidates with our own specialty sales force or with established partners.
- **Build a broad immunotherapy product pipeline with our innovative Viaskin technology platform.** We are leveraging our expertise in skin immunology science and believe that our Viaskin technology platform has the potential to support significant product opportunities beyond treatments for food allergies. To support our pipeline innovation strategy, we have completed proof-of-concept trials in the field of inflammatory and autoimmune diseases, including an investigator-sponsored study at the Children's Hospital of Philadelphia, or CHOP, in EoE, an inflammatory disease of the esophagus. In collaboration with the Geneva University Hospitals, or HUG, and BioNet-Asia Co. Ltd., or BioNet, we conducted a Phase I trial of Viaskin rPT for booster vaccination against pertussis, our first human proof-of-concept trial in the field of boosting vaccination.

Food Allergy

Unmet Medical Need

Food allergies are an increasingly common and serious disorder, with epidemiologic studies demonstrating an increasing prevalence over the last two decades. Reactions to foods in allergic patients are characterized by early onset symptoms and typically involve one or more target organs. Presentation can vary unpredictably, from mild symptoms to severe anaphylactic reactions. According to a paper published in the *Immunology and Allergy Clinics of North America*, food allergies are responsible for 150 to 200 deaths every year in the United States. The U.S. Centers for Disease Control and Prevention reported that food allergies result in more than 300,000 ambulatory-care visits per year among children under the age of 18. Every three minutes a food allergy reaction sends someone to the emergency department, which is about 200,000 emergency department visits per year, and every six minutes the reaction is one of anaphylaxis. A recent U.S. study indicates an increase of 350% in the number of hospitalizations of children below age 18 for diagnosis of a food allergy for the period from 2004 to 2006 as compared to the period from 1998 to 2000.

Among food allergies, peanut allergy is one of the most common, and the prevalence has increased over the past 20 years, especially in children. Exposure to peanut can cause unpredictable, severe and potentially fatal allergic reactions, including anaphylaxis. Peanut allergy affects 2.2% of all children under the age of 18 years in the United States, which is approximately 1.6 million children. Similar percentages of affected children have been reported in Europe and Australia. Among children with food allergies in the United States, 29% have peanut allergy, which makes it the most common food allergy in this age group. Peanut allergy is more likely to result in severe reactions than most other food allergies in children, and the majority of fatal anaphylactic reactions in patients are caused by peanut allergy.

Background on Allergic Reactions

An allergic reaction represents one type of an inappropriate immune response to a foreign substance, or an allergen. While, for most people, exposure to an allergen is relatively harmless, for others, exposure to an

allergen can provoke an allergic reaction of varying severity.

Prior to an allergic reaction occurring, an individual must be sensitized to the given allergen. Following allergen penetration of the body via the skin or the mucosa, for example, the eyes, respiratory or digestive tract, the immune system identifies the foreign element as dangerous and begins to produce specific antibodies against it. Antibodies, or immunoglobulins, are substances produced by the immune system that recognize certain foreign elements to which the body is exposed. There are five major types of immunoglobulins, or Ig: IgM, IgG, IgA, IgD, and IgE. When an individual produces IgE that is directed against a specific allergen (e.g. peanut protein), that individual is said to be sensitized and potentially clinically allergic. Upon re-exposure to the allergen, the now sensitized immune system is ready to react. IgE specifically directed against that allergen interacts with cells in the body, resulting in the release of substances that lead to the signs and symptoms of an allergic reaction such as redness, hives, itching, swelling, shortness of breath, vomiting, and cardiac arrhythmia. Reactions vary in duration and intensity, but occur reliably upon exposure to an allergen for an allergic individual, and reactions may progress if not treated. The most severe allergic reaction is anaphylaxis, which has been defined as a severe, potentially fatal, systemic allergic reaction occurring suddenly after contact with an allergen. If not treated quickly by epinephrine injection, anaphylaxis may progress to shock causing a rapid drop in blood pressure, loss of consciousness and possibly death within a few minutes.

Longer-term Impact of Allergic Reactions

While anaphylaxis is the most severe allergic reaction to food, patients also suffer from a lower quality of life. Symptoms tend to disappear within hours of exposure but, in some cases, can continue to affect patients for several days. Reactions can include, but are not limited to, skin discomfort, hay fever-like symptoms, impaired lung function and gastrointestinal complications, such as sustained bloating, nausea, vomiting and diarrhea. In some cases, food allergies can lead to chronic diseases such as failure to thrive in children and EoE.

In addition, recent studies suggest that patients with food allergies are especially at risk for experiencing significant disruption to their daily life. Food allergies are not only a physical disability; they are often associated with psychological traumas, including fear of eating, antisocial behavior and anxiety. In the case of pediatric patients, food allergies also have a significant impact on their caretakers. Based on our 2017 survey conducted of 500 parents with peanut-allergic children between the ages of 3 and 14 years, 73% of parents were most concerned with accidental exposure to peanuts in their child's daily life, 60% reported stress in their daily lives due to their child's peanut allergy, and 67% believed their child's allergy made it harder to be a parent.

Current Challenges in the Management of Peanut Allergy Patients

Current management options for peanut-allergic patients are limited. In peanut allergy, both children and caregivers experience anxiety related to the fear of accidental ingestion and fear of allergic reactions. Patients, health care professionals, caregivers, and society overall are dissatisfied with current management options.

Peanut allergy patients most often manage their allergy through strict avoidance of peanut; however, strict avoidance is very difficult to achieve, especially for children. In fact, 39% of peanut allergy patients experience an accidental exposure within a year of diagnosis. Some foods can contain hidden traces of allergens, labeling is often deceptive, and contamination of allergen-free foods occurs regularly. For example, according to a paper published in the *Journal of Allergy and Clinical Immunology*, or JACI, it is estimated that accidental exposure to peanuts in peanut allergic patients occurs once every three to five years and the annual incidence of accidental ingestion is between 15% and 40%. Any oral exposure to peanut has the potential to result in a severe reaction.

Epinephrine, also known as adrenaline, is the first-line treatment for anaphylactic reactions, most commonly administered by intramuscular injection. Epinephrine is available for self/caregiver auto injection in various proprietary forms. Allergic patients are instructed by their physicians on how to recognize the symptoms of anaphylaxis, how and when to use their autoinjector, and how to always have an autoinjector readily available.

Epinephrine injections help relieve the symptoms of anaphylaxis, but they do not treat or help address the underlying causes of the allergic disease.

Current Peanut Allergy Treatments and their Limitations

Allergen immunotherapy refers to a treatment approach that involves repeated administration of an allergen in an attempt to decrease reactivity in allergic patients. It is currently recognized by the World Health Organization, or WHO, as the preferred therapeutic treatment for allergies. Desensitization therapy is widely used in respiratory (inhalant) allergies and allergies to insect bites/stings (venom), and can also be performed for medication allergy. For inhalant and venom allergies, treatment is traditionally performed by subcutaneous injections of increasing doses of the allergen at regular intervals under the supervision of a physician.

Currently, oral and sublingual immunotherapy are used by some allergists to desensitize patients with food allergies. Both approaches expose the immune system to increasing amounts of allergen – either through powder that is ingested or serum that is administered under the tongue – until the patient can be exposed to a pre-determined amount of food without experiencing an allergic reaction. The FDA approved the first treatment for peanut allergy, Palforzia, an oral immunotherapy, in January 2020. Palforzia uses a formulation of peanut flour for oral administration intended to desensitize the patient to peanut.

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. Furthermore, in a third-party study of 200 peanut-allergic children, children expressed a preference for a patch treatment option over an oral treatment option, mainly due to perceived difficulty of oral therapy administration and fear of ingesting peanuts. Our clinical trials of Viaskin Peanut did not require restrictions to daily activities or require peanut ingestion. We believe Viaskin Peanut has distinct product attributes that may be important to patients with peanut allergy, their families and the allergists who treat them, and we believe they want and deserve multiple therapeutic options with distinct product profiles.

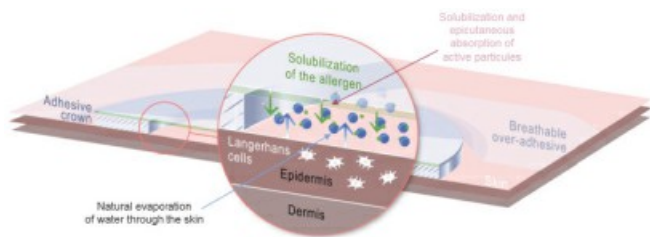
Our Viaskin Technology Platform

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

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

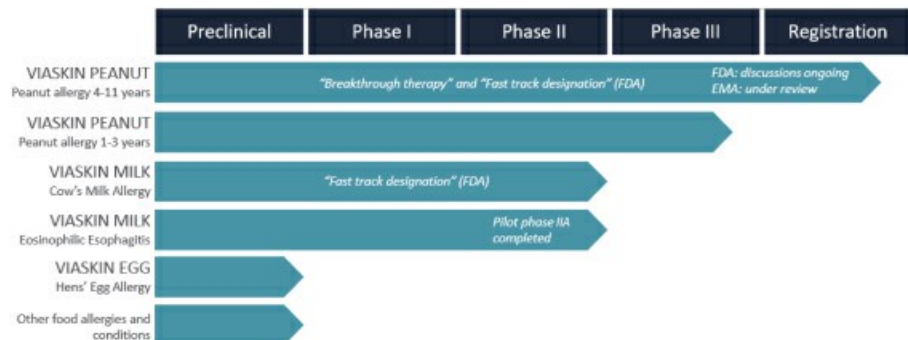
- Containing a dry layer of allergen in its center, the patch is positioned on intact skin, without prior preparation.
- The condensation chamber formed between the skin and the center of the patch creates hyperhydration of the skin and an accumulation of water.

- The accumulation of water solubilizes the allergen. Due to this condensation chamber, the epidermis becomes more permeable allowing passage of the allergen into the epidermis.
- Once in the epidermis, the allergen is captured by a population of highly specialized cells: Langerhans cells. These cells can take the protein at the surface of the skin, process it and present its epitopes to the lymphocytes in the lymph nodes.



Our Product Candidates

Our product development strategy is based on leveraging Viaskin’s scientific profile. 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:



* US FDA Breakthrough Therapy and Fast Track designation in children.

** US FDA Fast Track designation in pediatric patients two and older.

Viaskin Peanut for children ages 4-11

Our lead product candidate, Viaskin Peanut, has completed a global Phase III development program for the treatment of peanut allergic patients four to 11 years of age. The program comprised the following studies:

- *PEPITES (Peanut EPIT Efficacy and Safety Study)*, a randomized, placebo-controlled pivotal Phase III 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 III trial designed to generate safety data after six months of blinded treatment, as well as to evaluate the use of Viaskin Peanut 250 µg in routine clinical practice.

- *PEOPLE (PEPITES OPen Label Extension Study)*, a long-term, open-label extension trial of Viaskin Peanut 250 µg. In the PEOPLE trial, patients who were randomized and received active treatment during PEPITES received Viaskin Peanut 250 µg for two additional years, while patients who received placebo during PEPITES will be treated with Viaskin Peanut 250 µg for three years.

The results from PEPITES and REALISE formed the basis for our 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 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 Status

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, we announced that the FDA had 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.

On August 3, 2020, we received a Complete Response Letter, or CRL, from the FDA 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.

On January 13, 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. We believe the FDA feedback provides a well-defined regulatory path forward. In exchanges with the FDA, we proposed potential resolutions to two main concerns identified by the FDA in the CRL: the impact of patch adhesion and the need for patch modifications. 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 1/1000 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 has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. 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.

On March 11, 2021, we announced that we had commenced a trial in healthy adult volunteers to evaluate the adhesion of five modified Viaskin Peanut patches in order to identify the one or two best-performing patches. We

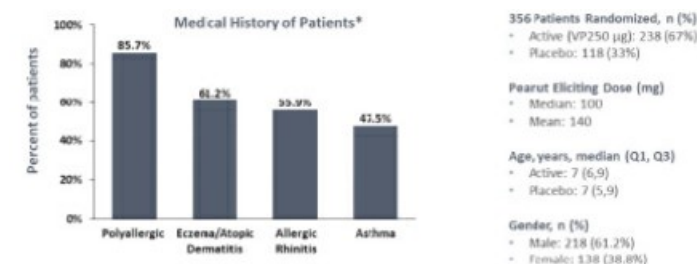
expect that this trial will be completed by the end of March. We intend to advance those patches selected for use in an allergen uptake, or protein transport, trial and adhesion and safety trial, and we intend to submit the protocols for these trials to the FDA for review and comments in the second quarter of 2021 before initiating the trials. We will address details about a new human factor, or HF, validation trial and additional CMC data in subsequent interactions with the FDA.

European Union Regulatory Status

On November 2, 2020, we announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut 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 4 to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, or EC, 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.

PEPITES (Peanut EPIT Efficacy and Safety Study)

In December 2015, we initiated a pivotal Phase III 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 III 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. During the trial, patients' sensitivity to peanut protein was assessed using a double-blind, placebo-controlled food challenge, or DBPCFC, at baseline and again after 12 months of treatment. The DBPCFC was halted once the patient exhibited an objective symptom, as described on a pre-specified scale, thus establishing a subject's peanut reactivity level, also known as the patient's eliciting dose, or ED. The median baseline reactive dose in PEPITES was 100 mg at baseline.

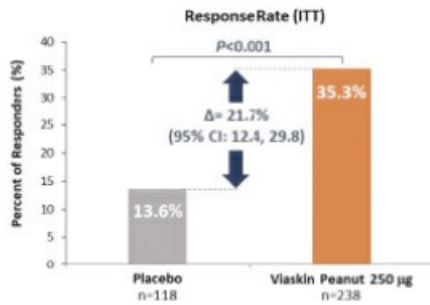


*Medical History of Patients is a summary of the trial population. VP250 µg patients: polyallergic=209 (88.2%), eczema/atopic dermatitis=139 (58.8%), allergic rhinitis=132 (55.5%), asthma=117 (49.2%), placebo patients: polyallergic=108 (92.4%), eczema/atopic dermatitis=57 (48.3%), allergic rhinitis=57 (48.3%), asthma=32 (26.3%).
 Diquarte V, VP250 µg Viaskin Peanut 250 µg.
 J. Pediatr. 2018; 184: 1001-1011. doi:10.1016/j.jpeds.2018.11.015.

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

Results of PEPITES Trial

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



Confidence Interval, ITT (Intention-to-Treat); 1. Feilicher DM, et al. JAMA. 2019; doi:10.1001/jama.2019.1113.

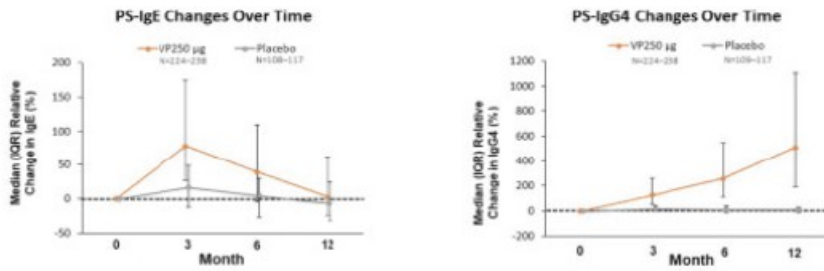
With respect to CRD, a key secondary endpoint which measures threshold reactivity during the DBPCFC, we observed that at month 12, patients treated with Viaskin Peanut 250 µg and placebo reached a mean CRD of 906 mg (median 444 mg) and 361 mg (median 144 mg) of peanut protein, respectively. Patients in the active and placebo arms entered the study 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, and immunoglobulin G4, orIgG4, support the immunomodulatory effect with Viaskin Peanut. The median observed increase from baseline in peanut-specific IgE was greater in the Viaskin Peanut group vs placebo group, respectively, at month 3 (70.1 kilounits of antibody per liter, or kUA/L vs. 9.8 kUA/L) and month 6 (27.4 kUA/L vs. 1.32 kUA/L). However, at month 12, peanut-specific IgE levels were observed to return to near baseline in

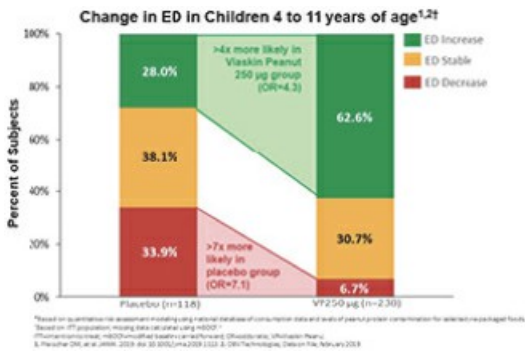
both groups (1.1 kUA/L vs. -1.1 kUA/L). Median peanut-specific IgG4 were observed to increase over time in the Viaskin Peanut group (change from baseline at month 3: 0.81 mg/L; month 6: 1.79 mg/L; month 12: 3.27 mg/L), while levels remained unchanged from baseline in the placebo group. The change from baseline in peanut-specific IgG4 was greater at all time points with Viaskin Peanut vs placebo, and the groups were observed to be highly distinguished by this marker, given a flat trend in the placebo arm. These changes are consistent with trends that have been observed with other forms of immunotherapy such as for venom and inhalant allergies.

PEPITES Immunological Responses



IQR=Interquartile range; PS=peanut-specific; VP=Viaskin Peanut
 L. Fleischer DM, et al. JAMA. 2019; doi:10.1001/jama.2019.1113. Z. OBN Technologies, Data on File, February 2019.

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



A favorable safety and tolerability profile was observed with Viaskin Peanut. Treatment adherence was high (98.5%), and similar discontinuation rates between treatment groups were reported, with 89.9% of patients completing the trial. There was a low discontinuation rate due to treatment-emergent adverse events, or TEAEs, (1.7%), and the overall rate of TEAEs, regardless of relatedness to the treatment, was comparable between treatment and placebo groups, at 95.4% and 89.0%, respectively. The most commonly reported TEAEs were

mild to moderate application-site reactions that decreased after month 1 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 (3.4%) of possibly or probably treatment-related anaphylaxis occurred, and all were classified as mild or moderate without evidence of cardiovascular, neurologic, or respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight patients continued on Viaskin Peanut in the trial.

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

PEOPLE (PEPITES OPen Label Extension Study)

In January 2020, we announced positive topline results of the three-year, open-label extension of our Phase III PEPITES trial, or PEOPLE trial, evaluating the long-term efficacy and safety of investigational Viaskin Peanut in peanut-allergic children ages 4 to 11 years. The results demonstrated long-term clinical benefit as shown by an increase in eliciting dose, or ED, which may decrease the chance of reacting to an accidental peanut exposure.

The PEOPLE trial is an ongoing open-label extension study evaluating the long-term safety, tolerability and efficacy of Viaskin Peanut 250 µg in patients who have completed the Phase III PEPITES trial. Of the 213 patients who were randomized in the active treatment arm of PEPITES and completed the 12-month trial, 198 patients opted to enter the PEOPLE study (safety population). Of these patients, 148 were considered completers after 36 months and 141 patients completed all treatment according to the study protocol without major deviations. Efficacy data were analyzed from these 141 patients (per-protocol).

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



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

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

REALISE (REAL Life Use and Safety of EPIT)

In November 2016, we initiated a Phase III trial in peanut-allergic children 4 to 11 years of age designed to assess the use and safety of Viaskin Peanut 250 μ g in routine clinical practice. REALISE is a multicenter, randomized 3:1, double-blind, placebo-controlled Phase III trial, in which pediatric peanut allergic patients were treated with Viaskin Peanut 250 μ g or placebo for six months. Treatment course with Viaskin Peanut consists of a daily application of the patch on the backs of the patients.

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

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

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

Results of REALISE Trial

Results from the 6-month blinded portion of this trial were comparable with outcomes from previous studies of Viaskin Peanut 250 μ g. The most commonly reported adverse events were local application site reactions, which were mostly mild and moderate in nature. No imbalance in SAEs was observed in the trial, with three cases in three patients in the active arm (1.0%) and two cases in two patients in the placebo arm (2.0%). One case in one patient in the active arm was qualified by the investigator as moderate anaphylaxis probably related to treatment. The patient responded to standard outpatient therapy. In the six-month blinded period, the discontinuation rate was 2.5%, with a 1.0% dropout related to adverse events. The mean patient compliance was above 95%.

Viaskin Peanut for Children ages 1-3

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

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

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

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

Viaskin Milk

Our second product candidate, Viaskin Milk, is in development for the treatment of cow's milk protein allergy, or CMPA, in children two to 17 years of age, and received fast track designation from the FDA in September 2016. In November 2014, we initiated a multi-center, double-blind, placebo-controlled, randomized Phase I/II dose-finding trial to study the safety and efficacy of Viaskin Milk in 198 patients with Immunoglobulin E, or IgE, mediated CMPA, which we refer to as the Milk Efficacy and Safety, or MILES, trial. The MILES (Milk Efficacy and Safety) study 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 I, for which the DSMB recommended to continue the study as planned and did not raise any safety concerns, and we launched Part B, or Phase II, in October 2015.

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

Viaskin Egg & Other Applications

In February 2015, we announced the development of a third product candidate, Viaskin Egg, for the treatment of patients suffering from hen's egg allergy. Preclinical development for Viaskin Egg commenced in the first half of 2015.

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 include vaccination for respiratory syncytial virus, as well as potential treatments for Crohn's disease, celiac disease and type I diabetes.

Following receipt of the CRL from the FDA in August 2020, we scaled down our Viaskin Egg and other clinical and pre-clinical programs in order to enable us to focus on the regulatory and clinical advancement of Viaskin Peanut in the United States and the European Union.

Diagnostic Tool Development

In an effort to continue diversifying our product candidate pipeline, we are also exploring the use of our technology platform in the development of diagnostic tools for food allergies. In May 2016, we announced our

entry into an exclusive global collaboration with Nestlé Health Science to develop MAGIC, a ready-to-use and standardized atopy patch test tool for the diagnosis of CMPA in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAGIC up through a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAGIC globally. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016. We are currently conducting a Phase II clinical trial of MAGIC.

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

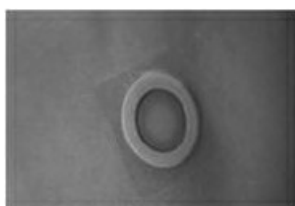
Potential Biomarker Applications

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

Manufacturing and Supply

Our Proprietary Viaskin Technology

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



This process sprays a liquid solution of electrically charged proteins onto the patch's backing, which is then turned into a dry solid charged particle, which remains 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:

- Constant liquid flows from a capillary and is subjected to a high voltage electric field.
- With our electrospray machine, we can transform these electrically charged liquid droplets into dry solid charged particles, and then drive them along the electric field lines onto the patch's backing.
- When the electric field lines are directed toward the grounded Viaskin patch, they force the dry particles to go directly to and only onto the patch.

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 and size 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 contract manufacturer, Sanofi, to manufacture the active pharmaceutical ingredients used in our Viaskin product candidates, such as peanut protein extract. Our manufacturing machine then uses an electrospray technology to deposit the active pharmaceutical ingredient onto the Viaskin patch.



ES GEN3.1 (2009)
10 or 18 nozzles
Used for Phase I and Phase II trials



ES GEN3.2 (2014)
54 nozzles
Used for Phase III trials
Improved electrospray process, forerunner of ES GEN4.0

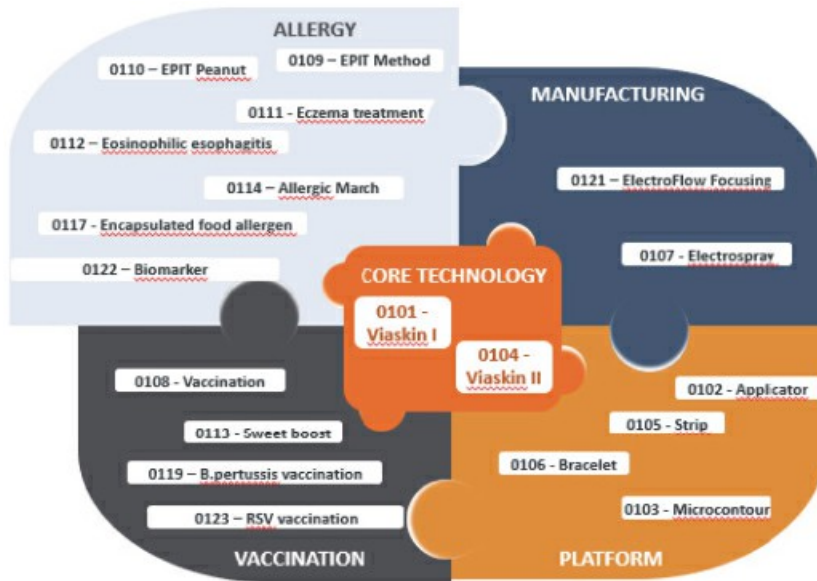


ES GEN4.0 (2017 & 2020)
288 nozzles
To be used for commercial products
Scalable to produce more patches annually

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 design, develop and build our manufacturing tools, and contract third-party manufacturers to operate it. We have entered into an agreement with a contract manufacturer, FAREVA, to manufacture clinical and commercial batches of Viaskin Peanut patches.

Intellectual Property

Our patent portfolio includes pending patent applications and issued patents in the United States and in foreign countries. To date, all patents directed at the Viaskin electrostatic patch, as well as food allergen desensitization methods, have been issued in the major markets, including in particular the United States, Europe, Canada and Australia. The diagram below represents our categories of patents or patent applications:



These patents and applications generally fall into four broad categories:

- patents and patent applications we co-own with AP-HP and the Université de Paris-Descartes relating to the Viaskin electrostatic patch and its use, half of which may expire as early as 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 AP-HP and the Université de Paris-Descartes relating to the treatment of peanut allergies using our Viaskin patch technology, which may expire as early as 2028; and
- a variety of other patent applications that we own or co-own relating, for example, to prophylactic uses of the Viaskin patch technology and to treatment of other indications using the Viaskin patch technology.

The term of a U.S. patent may be eligible for patent term extension under the Hatch-Waxman Act to account for at least some of the time the drug or device is under development and regulatory review. With regard to a drug or device for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug or device. 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 and when a Viaskin electrostatic 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 has extensive know-how and trade secrets covering part of the Viaskin patch manufacturing method using electrospray technology

Co-Ownership Agreement

AP-HP and Université de Paris-Descartes

In December 2008, we entered into an assignment, development and co-ownership agreement with AP-HP and Université Paris-Descartes, or UPD, by which we agreed to terms of co-ownership with AP-HP and UPD 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 UPD 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 UPD 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 UPD a percentage in the low single digits of the money that we receive from our licensee.

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

Any party may terminate the license in the event of another party's substantial breach which remains uncured after six months of receiving written notice of such breach. The agreement will also terminate in the event we cease operations or are subject to a dissolution or bankruptcy proceedings.

Absent early termination, the agreement will automatically terminate upon the expiration of the last shared patent. In the event the agreement is terminated, we would no longer have the exclusive right to commercial use of the shared patents, though we would retain our shared ownership rights. In addition, our ownership stake in certain jointly made improvements covered by the shared patents would survive termination of the agreement. The longest lived patent rights licensed to us under the agreement are currently expected to expire in 2029.

Competition

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Significant 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 or deny us marketing exclusivity rights. 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 of similar classes of products; (3) the effectiveness of sales, marketing, and distribution capabilities; and (4) the scope of any approval provided by the FDA or 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 candidate fail to gain regulatory approvals and acceptance in their intended markets, we may not generate meaningful revenues or achieve profitability.

There are numerous competitors on the market for the therapeutic treatment of allergies. Numerous structures, pharmaceutical laboratories, biotechnology companies, institutions, universities and other research entities are actively involved in the discovery, research, development and marketing of therapeutic responses to treat allergies. There are competitors in the food allergy space that have greater resources and experience in terms of clinical development, management, manufacturing, marketing and research than us.

In the case of food allergies, we are aware of several academic studies that are currently being conducted in major centers and hospitals worldwide. These studies are evaluating sublingual, subcutaneous, intranasal or other forms of desensitization or products using synthetic allergens, denatured allergens or combinations of medicines or methods, or medicines using traditional methods such as Chinese herbs. We are not aware of any pharmaceutical development in conjunction with these academic efforts at this time.

We expect studies combining other methods of immunotherapy, such as OIT, with anti-IgE treatments will be conducted. These types of co-administrations may significantly improve the safety of specific immunotherapies administered orally or subcutaneously, and may become significant competitors with our products.

To our knowledge, other pharmaceutical and biotechnology companies are also seeking to develop food allergy treatments, although many are in the discovery or preclinical stages. For example, Aimmune Therapeutics, Inc., or Aimmune, received FDA approval of its OIT product candidate, Palforzia, in peanut allergic patients in January 2020. Palforzia uses a formulation of peanut flour for oral administration intended for oral desensitization to peanut. We are also aware of other companies developing OIT product candidates, as well as other companies that are working on recombinant peanut proteins capable of initiating an attenuated immune response of using subcutaneous administration. In February 2020, Aimmune announced the licensing of exclusive worldwide rights to Xencor's XmAb®7195 to be developed in combination with Palforzia. Aimmune also announced a clinical collaboration with Regeneron Pharmaceuticals, Inc. and Sanofi to study Palforzia treatment with dupilumab in peanut allergic patients, and commenced a Phase II clinical trial in October 2018 under this collaboration. Regeneron and Sanofi are currently recruiting patients in a Phase II study of dupilumab as a monotherapy in the treatment of peanut allergic patients. Nestlé S.A., with whom we have an existing license and collaboration agreement, acquired Aimmune in October 2020. Aimmune will continue to function as a stand-alone business unit that will manage all of Nestlé's global pharmaceutical business. In August 2018, Genentech, Inc. and Novartis Pharmaceuticals Corporation announced that the FDA granted breakthrough designation for Xolair (omalizumab) for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies. In July 2019, the National Institute of Allergy and Infectious Diseases, or NIAID, started a Phase III clinical trial studying omalizumab as monotherapy and as adjunct therapy to multi-allergen OIT in multiple food allergies.

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

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

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial

sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or 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 in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion.

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase I 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 II clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase III clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase III clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of a BLA.

Post-approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or

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

BLA and FDA Review Process

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

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

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

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

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

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

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV 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

- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect. Our Viaskin product candidates are combination products comprising a device for delivery of a biologic. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the “primary mode of action” of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product.

Expedited Development and Review Programs

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

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

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

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

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

materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Designation

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

Pediatric Trials

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II 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 IV testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, 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.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration, and specifics of the FDA approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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, 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.

European Union Drug Development

In the European Union, our future product candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the European Union Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, a new Regulation No. 536/2014 on clinical trials on medicinal product candidates for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The new Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. The new Regulation was published on June 16, 2014 but should only be applied in December 2021 (its entry into application will occur after the publication of a notice delivered by the European Commission on the European Union clinical trial portal and database). Until then, the Clinical Trials Directive 2001/20/EC will still apply. In addition, the transitory provisions of the new Regulation offer the sponsors the possibility to choose between the requirements of the Directive and the Regulation for one year from the entry into application of the Regulation.

Under the current regime, before a clinical trial can be initiated, it must be approved in each of the European Union countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

As a result of the ongoing COVID-19 pandemic, the regulatory authorities in various countries (including the *Agence nationale de sécurité du médicament et des produits de santé*, or ANSM, in France) have published general recommendations and set up transitional measures during the first wave of the epidemic aimed at guaranteeing the continuity of drug development while ensuring the safety of clinical trial participants. The transitional measures may be reactivated depending on the evolution of the healthcare context and the needs identified for the various research sites.

European Union Drug Review and Approval

In the European Economic Area, or EEA, which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA (though there are other cases of regulatory authorizations derogating from the MA system which are exceptional and do not currently apply to us). There are four types of marketing authorizations procedures.

For the registration of a drug in more than one European Union Member State, the applicant can choose:

- The Centralized Procedure: an MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA on the date on which Regulation No. 726/2004 enters into force or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.
- The Mutual Recognition Procedure is mandatory when a product has already been authorized for marketing in a Member State of the EEA, known as the reference Member State, or RMS. This National MA needs to be recognized by the other Member States through the Mutual Recognition Procedure.
- The Decentralized Procedure: when the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMSs) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the CMSs).

For the registration of a medicinal product in only one Member State of the European Union, the applicant must use the national procedure. National marketing authorizations are issued by the competent authorities of the EEA Member States (e.g., for France, ANSM) and only cover their respective territories. They are available for products that are not covered by the compulsory scope of Community procedures.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

The EEA currently consists of the 27 Member States of the European Union as well as Norway, Iceland and Liechtenstein.

The pharmaceutical legislation of the European Union is no longer applicable in the United Kingdom as of January 1, 2021.

An Economic and Trade Partnership Agreement was concluded between the European Union and the United Kingdom on December 24, 2020. To date, this agreement does not provide for a principle of mutual recognition (i.e. the marketing authorization of a drug obtained in the European Union is not recognized in the United Kingdom, and vice versa). However, the Agreement does contain facilitation and cooperation arrangements, including an annex dedicated to medicinal products (*Annex TBT-2 on Medicinal Products*). In the meantime, regulatory authorities (such as the EMA at the European Union level or the ANSM in France) have published

recommendations intended for industrial stakeholders likely to be affected by Brexit, pending eventual technical agreements. Many aspects related to the development, marketing and commercialization of drugs (including drug manufacturing and supply chain) have been and are expected to continue to be impacted by Brexit.

Other Regulatory Matters

French Regulatory Framework

In the European Union – pending the effectiveness of Regulation No. 536/2014 – the regulation governing clinical trials is currently based on European Directive No. 2001/20/EC of April 4, 2001 with respect to the implementation of good clinical practices in the conduct of clinical trials on medicinal products for human use. Each European Union Member State had to transpose this Directive into national law by eventually adapting it to its own regulatory framework.

In France, for example, Directive No. 2001/20/EC has been transposed by Act No. 2004-806 of August 9, 2004 relative to the public health policy and Decree No. 2006-477, April 26, 2006, modifying chapter I, Title II, Book I of the first part of the Code of Public Health dedicated to biomedical research. This regulation replaces the notification procedure arising from the Huriet-Sérusclat Act of December 20, 1988. The Act of August 9, 2004 was notably amended by the Act of March 5, 2012 and by the ordinance of June 16, 2016, which mostly aims at (i) adapting the provisions relating to clinical research to the new European Regulation No. 536/2014, (ii) a better response coordination among Ethical Research Committees in charge of reviewing research agreements and (iii) harmonizing data protection provisions with the latest legislative developments (Jardé Act).

Article L. 1121-4 of the Public Health Code, as amended by the Ordinance of June 16, 2016, establishes a system of prior authorization issued by the ANSM and/or of a favorable opinion of a competent Ethical Research Committee, depending on the type of clinical trial. Since the entry into force of the Jardé Act, the competent Ethical Research Committee is selected randomly among available committees having the required jurisdiction to review the project by drawing lots (article L.1123-6 of the Public Health Code as amended by Law No. 2020-1525 of December 7, 2020). On the basis of Article L. 1123-7 of the same code, the Ethical Research Committee shall deliver its opinion on the research's conditions of validity, particularly with respect to participant protection, their information and how they collect informed consent, as well as the project's general relevance, the satisfactory nature of the assessment of benefits and risks and the adequacy between the objectives pursued and the means implemented. The ANSM, after submission of the complete file containing not only information on the clinical protocol, but also specific product data and its quality control, as well as results of pre-clinical studies may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of his research project and submit this amended or supplemented request to the ANSM. If the sponsor does not alter the content of its request, the request is considered rejected.

Under the terms of the Decree of April 26, 2006 (as modified by Decree No. 2016-1537 of November 16, 2016), the time limit for the examination of a request for authorization cannot exceed 60 days from the receipt of the complete file (Article R.1123-32 of the Public Health Code). Finally, under Article L. 1123-11, in the event of risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the Public Health Code, it may at any time request changes to procedures for the realization of research, and suspend or ban this research. As of October 15, 2018, the ANSM has implemented a fast-track system for the authorization of clinical trials ("Fast Track"), which will reduce the time required to process applications for authorization of clinical trials for medicines (for sponsors who meet the eligibility criteria) and for innovative therapy medicines, or ITMs, as of February 18, 2019. Fast Track 1, "Access to Innovation", provides for a maximum review time of 40 days for trials of new medicines and 110 days for ITMs. Fast Track 2, "Development Support", provides for a maximum review time of 25 days for trials of new medicines and 60 days for ITMs.

The decision of November 24, 2006 sets the rules for Good Clinical Practice, or GCP, for biomedical research on medicines for human use provided for in Article L. 1121-3 of the Public Health Code. The purpose of Good Clinical Practice is to ensure both the reliability of data arising from clinical trials and the protection of persons participating in these clinical trials. GCPs shall apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers and Phase II to IV clinical trials.

Personal data collected during clinical trials must be reported to the French data protection authority, and kept in the record of processing activities held by the data processor pursuant to the Regulation 2016/679 of April 27, 2016 (GDPR), French Act No. 78-17 of January 6, 1978, concerning computing, files and freedoms, and its implementing legislation. However, for certain types of research, the formalism is lightened if the data processing is carried out in compliance with one of the reference methodologies (RM) in force. In particular, the data controller who wishes to implement one or more processing operations in compliance with one of these reference methodologies must send the CNIL a declaration attesting to this compliance for each reference methodology applicable to its projects. On the other hand, if the study does not fall within the scope of these reference methodologies, the sponsor is obliged to submit a research authorization request to the CNIL. According to the aforementioned regulations, patients have, among others, a right to their data and a right of rectification of such data, as the case may be.

Regarding transfers of personal data between the European Union and the United States, the European Court of Justice has (i) invalidated the data protection shield known as the “Privacy Shield”, but (ii) held the European Commission’s standard contractual clauses regarding personal data transfers to be valid (as set forth in Commission Decision 2010/87/EU of February 5, 2010, amended in 2016) in the “Schrems II” decision of July 16, 2020 (CJUE, July 16, 2020, C-311/18).

French Pharmaceutical Company Status

By official letters of the ANSM dated August 23, 2017 and June 4, 2019, the Company has been granted by the ANSM the status of pharmaceutical establishment (“*établissement pharmaceutique*”) solely for the purpose of conducting quality control and release activities for its future therapeutic patches on the Bagneux site. Obtaining the pharmaceutical establishment license, either as distributor “exploitant” or as manufacturer, requires the submission of a request electronic file via the dedicated platform (mandatory since January 1, 2020) specific to each of the two qualifications with the ANSM, which only grants it after review of this file and evaluation, usually after verification that the company has adequate premises, the necessary personnel and an adapted structure with satisfactory procedures for carrying out the proposed pharmaceutical activities.

In order to simplify the procedures for authorizing pharmaceutical companies manufacturing new and/or innovative medicines to operate in France, the ANSM has introduced a new procedure to reduce the time required to process an application from 90 to 60 days.

We currently entrust CMOs with the manufacturing of clinical batches and intend to continue relying on CMOs for the production of the first commercial batches.

Reimbursement

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

In order to secure coverage and reimbursement for any product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our product candidates may not be considered medically necessary or cost-effective. A third-party payor’s decision to provide coverage for a drug product does not imply that an adequate

reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our product candidate or a decision by a third-party payor to not cover our product candidate could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

For example, the ACA, enacted in March 2010, has significantly impacted 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.

While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, on December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017, or Tax Act, which included a provision repealing the individual mandate to maintain health insurance coverage under the ACA, effective January 1, 2019. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA. We continue to evaluate how the ACA and recent efforts to limit the implementation of the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction was tasked with recommending to Congress proposals in spending reductions. Because they did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, it triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per

fiscal year, which went into effect in April 2013 and will stay in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 unless additional Congressional action is taken. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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 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. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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

In France, for example, effective access to the market can be achieved either at a free price, decided by the pharmaceutical company, or with a system of cover/reimbursement with a price regulated by the authorities. In this case, the future products must be included, for coverage by hospitals, on the list of proprietary medicinal products approved for use by local authorities and various public services (known as the “*Liste Collectivités*”) (Article L. 5123-2 of the Public Health Code) or included on the list of proprietary medicinal products reimbursable to insured persons (known as the “*Liste Sécurité Sociale*”) for reimbursement by the Social Security system (Article L. 162-17 of the Social Security Code).

Indeed, in France, the manufacturer’s price excluding tax of medicines reimbursable to insured persons (registered on the Social Security List) is the subject of a multi-year agreement negotiated between each pharmaceutical company and the Economic Committee for Health Products, or CEPS (failing this, by unilateral decision of the CEPS). A framework agreement has been concluded between LEEM (the trade union representing the pharmaceutical industries) and CEPS. The last framework agreement was signed on December 31, 2015 and will remain in force until July 31, 2020. 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 marketing approval. The healthcare laws and regulations that may affect our ability to operate include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. The intent standard under the federal Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, which impose penalties and provide for civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations, and, beginning in 2022, will require applicable manufacturers to report information regarding payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives;
- HIPAA, as amended by the HITECH Act, and its implementing regulations, which imposes certain requirements on covered entities and their business associates, and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information; and
- state, local and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by pharmaceutical sales representatives; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

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, 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.

Within the European Union, there are also national anti-corruption procedures and specific rules on ethics.

Employees

As of December 31, 2020, we had 141 full-time employees and 1 part-time employee, including around 20 with M.D. or Ph.D. degrees. Of these employees, 13 employees are engaged in research and development activities and 44 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.dbvtechnologies.com>. We make available on our website, free of charge, our Annual Report 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. The information found on our website is not incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

Item 1A. Risk Factors.

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

Risks Related to Our Financial Condition and Capital Requirements

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

We are a clinical-stage biopharmaceutical company, and we have not yet generated significant income from operating activities. We have incurred net losses in each year since our inception in 2002, including net losses of \$172.0 million and \$159.6 million for the years ended December 31, 2019 and 2020 respectively. As of December 31, 2020, we had an accumulated deficit of \$958.5 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 and marketing approvals and pursue commercial activities for Viaskin Peanut, for which our Marketing Authorization Application, or MAA, is currently under review by the European Medical Agency, or EMA; and for which we continue to seek regulatory and marketing approvals in the United States;
- continue our research, pre-clinical and clinical development of our product candidates, including additional trials related to our pursuit of regulatory approval of Viaskin Peanut in the United States;
- seek regulatory and marketing 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 marketing 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, for our approved products, if any;
- initiate additional pre-clinical, clinical or other studies for our other product candidates;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain new and existing skilled personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts, as well as a company listed on both the U.S. and French stock markets; and
- experience any delays or encounter issues with any of the above.

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

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

We are currently advancing our product candidates through pre-clinical and clinical development. Developing product candidates is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we seek regulatory approval for Viaskin Peanut. Furthermore, if we obtain marketing 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, 2020, our cash and cash equivalents were \$196.4 million. We have primarily funded our operations through equity financings, and by obtaining public assistance in support of innovation and reimbursements of research 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.

In October 2019, we announced the FDA's acceptance for review of our Biologics License Application for Viaskin Peanut, with a target action date, provided by the FDA, of August 5, 2020. On March 16, 2020, we announced that the FDA has informed us that during its ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. On August 3, 2020, we received a Complete Response Letter, or CRL, from the FDA 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.

On January 13, 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. We believe the FDA feedback provides a well-defined regulatory path forward. In exchanges with the FDA, we proposed potential resolutions to two main concerns identified by the FDA in the CRL: the impact of patch adhesion and the need for patch modifications. 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, including the peanut protein dose of 250 µg, 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 has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. 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 intend to submit the protocols for the safety and adhesion study and the allergen uptake study to the FDA for review and comments in the second quarter of 2021 before initiating the trials. We will address details about a new human factor, or HF, validation study and additional CMC data in subsequent interactions with the FDA.

On November 2, 2020, we announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut 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 4 to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, or EC, on whether to grant a marketing authorization.

We expect our operating losses to continue for the foreseeable future. Based on our current operations, plans and assumptions, we expect our current cash-on-hand and cash equivalents, to be sufficient to fund our operating plans to the second half of 2022.

We expect that we will need to raise substantial additional capital in the future as we commercialize Viaskin Peanut, if approved, and continue to discover and develop other product candidates using our Viaskin Platform. 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. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives. The COVID-19 pandemic has already resulted in a significant disruption of global financial markets. If the disruption persists and deepens, whether as a result of the ongoing COVID-19 pandemic or otherwise, we could experience an inability to access additional capital.

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

Additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs or ordinary shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The 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 candidate 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 5% 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 April 20, 2020 granted authority to our board of directors to increase our share capital up to 30% of issued share capital, if the investors in such offering fit within a category 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 average trading price on Euronext Paris over five consecutive trading days chosen among the last thirty trading sessions preceding the commencement of the marketing of the transaction or (ii) the weighted average trading price the day preceding the commencement of the marketing of the transaction.

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 ongoing 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 causing significant disruption in the operations and business of third-party manufacturers, CROs, other services providers, and collaborators with whom we conduct business.

In response to the COVID-19 pandemic, many state, local and foreign governments, including the French and U.S. governments, put in place quarantines, executive orders, shelter-in-place or stay-at-home orders and similar government orders and restrictions in order to control the spread of the disease. While some restrictions have recently been relaxed, others have re-imposed following prior relaxation as a result of continually evolving incidence and rates of infection. Such orders or restrictions, or the perception that such orders or restrictions could occur or continue for a protracted period of time, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions and cancellation of events, among other effects that could negatively impact productivity and disrupt our business and those of third-party manufacturers, CROs, other services providers, and collaborators with whom we conduct business. While the rollout of vaccines has begun, the timing of vaccinations, lifting of movement restrictions, and reinstatement of in-person events is unknown.

As a result of the COVID-19 pandemic, certain of our employees continue to work remotely. We have prepared plans to reopen our offices to allow employees to return to the office, which will be based on a phased approach. However, in light of continually changing circumstances regarding infection rates and local government recommendations, we may be required to suspend or reverse any planned return to the office in the future. Additionally, we may experience disruptions if our employees become ill, despite the availability of vaccines, and are unable to perform their duties. The effects of any of our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

In addition, our ability to conduct clinical trials has been and may continue to be affected by the COVID-19 pandemic. For example, we have experienced slower than anticipated clinical site activation and patient enrollment in our MAGIC trial conducted as part of our collaboration with Nestlé. 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, including vaccination efforts, or new or renewed shelter-in-place or stay-at-home orders. 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 have affected the broader economies and financial markets, triggering an economic downturn, which has at points adversely affected, and could

again adversely affect, our ability to access capital, which could negatively affect our business. In addition, a 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, as the situation continues to evolve. The full extent of COVID-19's impact on our clinical development and other operations and financial performance depends on future 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 may require additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the scope, progress in, results and the costs of, our pre-clinical studies and clinical trials and other research and development programs, particularly as we seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials;

- the approval of Viaskin Peanut by the EMA, FDA or other regulatory agencies;
- the costs of 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, 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.

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

In addition to the development of our lead product candidates, we have completed and commenced a number of proof-of-concept trials in the field of inflammatory and autoimmune diseases. In November 2015, Dr. Jonathan Spergel from the Children’s Hospital of Philadelphia, or CHOP, initiated the Study of Viaskin Milk in MILK-Induced Eosinophilic Esophagitis, or SMILEE, a Phase IIa clinical trial assessing the safety and efficacy of Viaskin Milk for the treatment of milk-induced eosinophilic esophagitis, with findings presented in December 2018 and February 2019. We also investigated the use of Viaskin rPT for the reactivation of immunity against *Bordetella pertussis* (whooping cough) in healthy adults. Following the announcement of additional Phase I clinical trial results in September 2018, we evaluated further development pathways, including the optimization of Viaskin rPT. Our current early-stage development programs also include potential treatments for Crohn’s disease and respiratory syncytial virus. These development programs are still in the pre-clinical or proof-of-concept phase, have been scaled down in 2020, and may not result in product candidates that we can advance to the clinical development phase. None of our other potential product candidates have commenced

clinical trials, and there are a number of U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, regulatory requirements that we must satisfy before we can commence these clinical trials, if at all. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other early-stage development programs may adversely affect our ability to continue development and commercialization of product candidates based on our Viaskin technology platform, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. Even if we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or the EMA.

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, and particularly during 2021, our first year filing reports with the SEC on U.S. domestic issuer forms, 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. We have limited experience complying with Section 404, and such compliance 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 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.

In October 2019, we announced the FDA's acceptance for review of our Biologics License Application for Viaskin Peanut, with a target action date, provided by the FDA, of August 5, 2020. On March 16, 2020, we announced that the FDA has informed us that during its ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. On August 3, 2020, we received a Complete Response Letter, or CRL, from the FDA 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.

On January 13, 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. We believe the FDA feedback provides a well-defined regulatory path forward. In exchanges with the FDA, we proposed potential resolutions to two main concerns identified by the FDA in the CRL: the impact of patch adhesion and the need for patch modifications. 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, including the peanut protein dose of 250 µg, 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 has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. 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 intend to submit the protocols for the safety and adhesion study and the allergen uptake study to the FDA for review and comments in the second quarter of 2021 before initiating the trials. We will address details about a new human factor, or HF, validation study and additional CMC data in subsequent interactions with the FDA.

On November 2, 2020, we announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut 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 4 to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, or EC, on whether to grant a marketing authorization.

Even if we successfully commercialize Viaskin Peanut, we may not be successful in developing and commercializing our other product candidates, including Viaskin Milk, and our commercial opportunities may be

limited. We have currently scaled down our research and clinical development efforts related to our product candidates other than Viaskin Peanut.

Viaskin Milk will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence its commercialization. Our other product candidates, such as Viaskin Egg or Viaskin rPT, 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 studies to satisfy both U.S. and EMA requirements, which will require the expenditure of substantial resources. Of the large number of drugs in development in the United States, only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

We are not permitted to market any Viaskin product in the United States until we receive approval of a BLA from the FDA, or in any other countries until we receive the requisite approval from such countries' regulatory bodies. Obtaining requisite marketing approval in any country, is a complex, lengthy, expensive and uncertain process, and the FDA or the applicable foreign regulatory agency 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 Viaskin product is a safe and effective treatment, to the satisfaction of the FDA or the applicable foreign regulatory agency;
- 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 agency for marketing approval;
- the FDA or the applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or the applicable foreign regulatory agency may require that we conduct additional clinical trials;
- the FDA or the applicable foreign regulatory agency may not approve the formulation, labeling or specifications of a Viaskin product;
- 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 agency may find the data from pre-clinical studies and clinical trials from a Viaskin product insufficient to demonstrate that the clinical or other benefits of either product candidate outweighs its respective safety risks;
- the FDA or the applicable foreign regulatory agency may disagree with our analysis or interpretation of data from our pre-clinical studies and clinical trials;
- the FDA or the applicable foreign regulatory agency 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 agency require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA or the applicable foreign regulatory agency may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may restrict the use of our products to a narrow population;
- the FDA or the applicable foreign regulatory agency 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 agency may change its approval policies or adopt new regulations. 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 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 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.

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 promising 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 approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business and financial condition and on the value of our ADSs and ordinary shares.

In connection with clinical testing and trials, we face a number of risks, including:

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested, especially during the double-blind, placebo-controlled food challenges;
- extension studies on long-term tolerance could invalidate the use of our product, showing Viaskin does not generate a sustained protective effect;
- the results may not confirm the positive results of earlier testing or trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies 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. The prior clinical trials of our product candidates based on our Viaskin technology platform showed favorable safety and efficacy data; however, we may have different enrollment criteria in our future clinical trials. As a result, we may not observe a similarly favorable safety and efficacy profile as our prior clinical trials. 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 promising 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 often 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 a marketing application may be submitted to the FDA or an applicable foreign regulatory agency. For example, the FDA has advised us that additional clinical testing of Viaskin Peanut will be required for evaluation of our BLA of Viaskin Peanut. 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 a marketing application to a regulatory agency, such as a NDA or a BLA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed.

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

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

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

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. The completion of trials for Viaskin Peanut or our other product candidates may be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs, and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;

- obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials;
- manufacturing sufficient quantities of a product candidate;
- obtaining permission to proceed from the FDA under an investigational new drug, or IND, application, or foreign equivalent approval from regulatory authorities outside the United States;
- obtaining institutional review board, or IRB, or independent ethics committee approval to conduct a clinical trial at a prospective clinical trial site;
- determining dosing and clinical design and making related adjustments; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial, and which has been impacted by the ongoing COVID-19 pandemic.

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

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation;
- serious adverse events relating to the double-blind, placebo-controlled food challenge procedure when testing patients for the sensitivity of their allergies;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as the ongoing COVID-19 pandemic or any other pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory agencies.

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

In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, or changes in FDA or other similar foreign regulatory agency policy or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn. Delays or failures in obtaining regulatory approvals may result in:

- varying interpretations of data and commitments by the FDA and similar foreign regulatory agencies; 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:

- diminishment of any competitive advantages that such product candidates may have or attain;
- delays or termination in clinical trials or commercialization;
- refusal by the FDA or similar foreign regulatory agencies to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties, and criminal prosecutions.

If our product candidates are not approved by the FDA, we will be unable to commercialize them in the United States.

The FDA must approve any new drug or biologic before it can be commercialized, marketed, promoted or sold in the United States. We must provide the FDA with data from pre-clinical studies and clinical trials that demonstrate that, among other things, our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We must provide data to ensure the identity, strength, quality and purity of the drug substance and drug product. Also, we must assure the FDA that the characteristics and performance of the clinical batches will be replicated consistently in the commercial batches. We will not obtain approval for a product candidate unless and until the FDA approves a BLA, if at all.

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

A fast track designation by the FDA 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 marketing approval.

We have obtained fast track designation from the FDA for the development of Viaskin Peanut and Viaskin Milk in pediatric populations, and we may pursue that designation for other product candidates as well. If a product is

intended for the treatment of a serious or life-threatening 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 whether or not to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do have fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track designation affords the possibility of rolling review, enabling the FDA to review portions of our marketing application before submission of a complete application, and priority review if supported by clinical data at the time of our BLA submission. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

The 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 marketing 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 marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing.

On November 2, 2020, we announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut 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 4 to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, or EC, on whether to grant a marketing authorization.

We may, in the future, conduct clinical trials for, and seek regulatory approval to market, other 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 Europe, we will be required to submit an MAA to the EMA which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and 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 health 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, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

Even if we, or our collaborators, obtain marketing 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 the patient population that may utilize the product or may be required 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 marketing 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 marketing 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.

Any of our product candidates for which we, or our collaborators, obtain marketing 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 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 marketing 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 to ensure that the benefits of a drug or biological product outweigh its risks.

The FDA or foreign regulatory authorities may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long-term observational studies on natural exposure. The FDA and other agencies, including the Department of Justice, 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 imposes 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 marketing 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.

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

We sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing 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 regulatory agencies and the timing thereof;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;

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

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, the trading price of the ADSs or ordinary shares may decline. For example, immediately following our August 3, 2020 announcement of our receipt of the CRL from the FDA related to our BLA for Viaskin Peanut, the trading price of our ADSs declined 43%.

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

We are dependent on third parties for the supply of various materials, chemical or biological products that are necessary to produce patches for our clinical trials or diagnosis patches, and will be necessary to produce patches for our commercial supply, if Viaskin Peanut is approved. The supply of these materials could be reduced or interrupted at any time, including as a result of shelter-in-place, stay-at-home or similar orders or other impacts due to the ongoing COVID-19 pandemic. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If key suppliers or manufacturers are lost or the supply of materials is diminished or discontinued, we may not be able to continue to develop, manufacture and market our product candidates or products, if any, in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products, if any, in a cost-effective and timely manner. To prevent such situations, we intend to diversify our supply sources by identifying at a minimum a second source of supply for critical raw materials and materials, such as natural protein and polymer film with a titanium coating. If we encounter difficulties in the supply of these materials, chemicals or biological products, if we were not able to maintain our supply agreements or establish new agreements to develop and manufacture our products in the future, our business, prospects, financial condition, results and development could be significantly affected.

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

Developing and commercializing new medicines entails significant risks and expenses. Our clinical trials may be delayed if third-party manufacturers are unable to assure a sufficient quantity of the drug product to meet our study needs. Currently, we have only one manufacturer, Sanofi S.A., or Sanofi, of the active pharmaceutical ingredients, or API, used in our Viaskin product candidates, including Viaskin Peanut, such as peanut protein extract and unmodified allergen milk extract. In February 2020, Sanofi announced that it plans to create a new company dedicated to the production and marketing to third parties of API, which will consolidate Sanofi's API commercial and development activities currently 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 trials may be delayed. Further, we are aware that Sanofi has entered into a clinical collaboration with Regeneron and Aimmune Therapeutics, to evaluate treatment with Palforzia in combination with Dupilumab in peanut allergic patients, and commenced a

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

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

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Any manufacturers with which we contract are required to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch of products based on our product candidates into the market. Moreover, the constituent parts of a combination product retain their regulatory status (as a biologic or device, for example) and, as such, we or our contract manufacturers 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. Failure by third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, revocation or suspension of marketing approval for any products granted pre-market approvals, 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 marketing 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 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. 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 persuade adequate numbers of physicians to prescribe 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, as we are currently exploring for the marketing 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 marketing approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing Viaskin Peanut or any of our other product candidates, either on our own or through collaborations with one or more third parties, our business, results of operations, financial condition and prospects will be materially and adversely affected.

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

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

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

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for biosimilar or interchangeable competition sooner than anticipated. Moreover, the process by which an interchangeable product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products (*i.e.*, drugs) is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing and subject to interpretation.

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, physicians may choose to restrict the use of the product if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives marketing 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 laboratories, biotechnology companies, institutions, universities and other research entities are actively involved in the discovery, research, development and marketing of therapeutic responses to treat allergies, making it a highly competitive field. We have competitors in a number of 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 young children, established competitors may invest heavily to quickly discover and develop novel compounds that could make the Viaskin patch products 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 Viaskin patch products. 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 academic studies that are currently being conducted in major centers and hospitals worldwide. These studies are evaluating sublingual, subcutaneous, intranasal or other forms of desensitization or products using synthetic allergens, denatured allergens or combinations of medicines or methods, or medicines using traditional methods such as Chinese herbs. We are not aware of any pharmaceutical development in conjunction with these academic efforts at this time.

We expect studies combining other methods of immunotherapy, such as oral immunotherapy, or OIT, with anti-IgE treatments will be conducted. These types of co-administrations may significantly improve the safety of specific immunotherapies administered orally or subcutaneously, and may become significant competitors with our products.

To our knowledge, other pharmaceutical and biotechnology companies are also seeking to develop or have received marketing approval for food allergy treatments. For example, Aimmune Therapeutics, Inc. acquired by Nestlé Health Science in October 2020, received FDA and EMA approvals of its OIT product candidate, Palforzia, in peanut allergic patients in January and December 2020. To our knowledge, Palforzia uses a formulation of peanut flour for oral administration intended for oral desensitization to peanut. We are also aware of other companies developing OIT product candidates, as well as other companies that are working on recombinant peanut proteins capable of initiating an attenuated immune response of using subcutaneous administration. Aimmune also announced a clinical collaboration with Regeneron Pharmaceuticals, Inc. and Sanofi to study Palforzia treatment with dupilumab in peanut allergic patients, and commenced a Phase II clinical trial in October 2018 under this collaboration. Regeneron and Sanofi are currently recruiting patients in a Phase II study of dupilumab as a monotherapy in the treatment of peanut allergic patients. In August 2018, Genentech, Inc. and Novartis Pharmaceuticals Corporation announced that the FDA granted breakthrough designation for Xolair (omalizumab) for the prevention of severe allergic reactions following accidental exposure to one Xolair or more foods in people with allergies. In July 2019, NIAID started a Phase III clinical trial studying omalizumab as monotherapy and as adjunct therapy to multi-allergen OIT in multiple food allergies.

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

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

- our ability or our collaborators' ability to set a price we believe is fair for our products, if approved;

- our ability or our collaborators' ability to obtain and maintain market acceptance by the medical community and patients;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale 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 and the Health Care and Education Reconciliation Act, or ACA, were designed to impact the provision of, or payment for, health care in the United States, including expanded Medicaid eligibility, subsidized insurance premiums, provided incentives for businesses to provide health care benefits, prohibited denials of coverage due to pre-existing conditions, established health insurance exchanges, and provided additional support for medical research. With regard to biopharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. However, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017, or Tax Act, which includes a provision repealing the individual mandate to maintain health insurance coverage under the ACA effective January 1, 2019. In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA. We continue to evaluate how the ACA and recent efforts to limit the implementation of the ACA will impact our business.

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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the Trump administration's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. 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 agencies 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 payers, as well as patient communities.

Recommendations by government agencies 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 payers. In July 2019, ICER published its final report assessing the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin Peanut and a competitor product candidate. The results of this or future ICER report or any similar recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use or reimbursement of Viaskin Peanut, if approved, could have a material adverse effect on our results of operations and financial condition. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of Viaskin Peanut, if approved, could adversely affect the market price of our securities.

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

Our product candidates are being developed to address the needs of severely allergic patients, for some of whom coming into contact with even minute amounts of an allergen can have a profound and life-threatening adverse reaction. Accordingly, safety is of paramount importance in developing these product candidates. To date, more than ten clinical trials of Viaskin Peanut and Viaskin Milk product candidates have been conducted both outside and inside of the United States in over 1,000 human patients to evaluate the safety and efficacy of these product candidates for the treatment of peanut allergies and milk allergies, respectively. Adverse events observed in these clinical trials have primarily involved general disorders such as skin and subcutaneous tissue, immune system and administration site conditions, such as erythema, pruritus, edema and urticaria. However, in clinical trials to date, one case of mild to moderate anaphylaxis has been reported, and it is possible that anaphylaxis or other systemic reactions may occur in the future. It is worth noting that, as a desensitization patch bringing the allergen into contact with the skin, reactions, which are a source of itching and discomfort for the patient, are common. This reaction is typically temporary in duration and fades after a few weeks of use. In addition, during daily administration of the patches during treatments, depending on the severity of the allergies and patient response to treatment, precautionary measures are necessary when handling the patches after use due to risk of contamination.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, halt or terminate clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Further, if our Viaskin patch product candidates receive marketing 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 markets within and without the United States and Europe. If we commercialize product candidates based on our Viaskin technology platform in foreign markets, we would be subject to additional risks and uncertainties, including:

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

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

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

Healthcare providers, physicians 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 marketing 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) 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. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives.

- 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.

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, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could substantially disrupt our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If the physicians or other providers or entities with

whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

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

Changes in regulatory requirements, FDA guidance or guidance from certain European regulatory authorities or unanticipated events during our clinical trials may force us to amend clinical trial protocols or the FDA or certain European 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 for review and approval, 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.

For example, in August 2020, the FDA identified concerns regarding the impact of patch-site adhesion on efficacy for Viaskin Peanut and indicated the need for patch modifications, and subsequently a new human factor

study. Following subsequent interactions with the FDA, order to confirm the consistency of efficacy data between the existing and a modified patch, FDA has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. 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 intend to submit the protocols for the safety and adhesion study and the allergen uptake study to the FDA for review and comments in the second quarter of 2021 before initiating the trials.

The FDA and other regulatory agencies 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 regulatory agencies 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 regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for Viaskin patch products as a treatment for a particular allergy, physicians, in their 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 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 such off-label uses, 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 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.

Our product development programs for candidates other than Viaskin patch products 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 common food allergies. In addition to the commercialization of Viaskin Peanut, if approved, we may pursue development of our other development programs, including Viaskin Milk, Viaskin Egg and Viaskin rPT. None of our other potential product candidates has commenced any clinical trials, we have scaled down our research and clinical development efforts related to these product candidates in order to focus on Viaskin Peanut, and there are a number of FDA 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. Any time, effort and financial resources we expend on our other development programs may adversely affect our ability to continue the commercialization of Viaskin Peanut, if approved, and the clinical development and commercialization of other Viaskin product candidates and 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. 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, as well as to commercialize and manufacture product candidates outside of food allergies. 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 allergies, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our product candidates is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;

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

Even if we have or obtain patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the allergy treatment field in which we are developing products. These could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

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

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

The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical

compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

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

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

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

From time to time, the United States Supreme Court, or the Supreme Court, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business.

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

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 expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of

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

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

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

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

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

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or

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

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

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

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

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

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

There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Organization, Structure and Operations

We are in the process of implementing a global restructuring program, and we may not be able to realize the anticipated benefits of this program or any other efforts to preserve operational flexibility and financial resources.

We initiated a global restructuring plan in June 2020 in order to provide operational latitude to progress the clinical development and regulatory review of investigational Viaskin Peanut in the United States and European Union. The full implementation of the restructuring plan will result in a reduction of more than 200 jobs, and our new organizational structure is designed to generate cost efficiencies, in particular through right-sizing our facilities and gathering our staff in one central office per country. However, there can be no guarantee that we will be able fully to implement our restructuring plans or to realize all of the anticipated benefits thereof. While we are seeking to terminate certain facilities leases and sublet other facilities, we may not be successful in doing so. If we are unable to fully implement our restructuring plan, we may not have sufficient financial resources to conduct necessary operations or otherwise capitalize on our business opportunities, and our business, financial condition and results of operations could be materially adversely affected.

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

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

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

We may incur significant costs from class action litigation.

The market price for our ordinary shares or ADSs may 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, on January 15, 2019, Travis Ito-Stone individually and on behalf of all others similarly situated, filed a class action complaint for violation of federal securities laws against us, our former Chief Executive Officer, our current Chief Executive Officer, our former Deputy Chief Executive Officer and our former Chief Business Officer in the United States District Court for the District of New Jersey. Subsequently, Ruth Pruitt and Asdrubal Delgado were appointed as lead plaintiffs and an amended complaint was filed on January 24, 2020 and a second amended complaint was filed on June 5, 2020. The operative complaint purports to bring a federal securities class action on behalf of a class of persons who acquired our securities between February 14, 2018 and March 16, 2020 and seeks to recover damages caused by defendants' alleged violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaint alleges, among other things, that the defendants made materially false and/or misleading statements related to our business, operational and compliance policies. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. See the section of this Annual Report titled "Legal Proceedings" for additional information on this matter.

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

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 with a €15.0 million (equivalent to \$18.4 million using closing exchange rate) annual aggregate coverage limit. 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 (*crédit d'impôt recherche*), or CIR. The CIR is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess (if any) may be refunded at the end of a three fiscal-year period. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented \$10.9 million and \$9.9 million, as of December 31, 2019 and 2020 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 forced to repay conditional advances prematurely if we fail to comply with our contractual obligations under the applicable innovation grant agreements.

Since inception through December 31, 2020, we have received multiple conditional advances totaling around 5 million dollars for innovation granted by OSEO, the French Agency for Innovation and part of the Banque Publique d'Investissement. If we fail to comply with our contractual obligations under the applicable innovation grant agreements, including if we lose our exclusive right to commercially develop our product candidates, we could be forced to repay the sums advanced ahead of schedule. Such premature repayment could adversely affect our ability to finance our research and development projects. In addition, we cannot ensure that we will then have the additional financial means needed, the time or the ability to replace these financial resources with others.

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. Compliance 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.

Our internal computer systems, or those of our third-party contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure, accident or security breach to date, including cybersecurity incidents, if such an event were to occur and cause interruptions in our operations, it 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. To the extent that any disruption or security breach, including cybersecurity incidents, results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. As these threats continue to evolve, particularly around cybersecurity, we may be required to expend significant resources to enhance our control environment, processes, practices and other protective measures. Despite these efforts, such events could materially adversely affect our business, financial condition or results of operations.

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

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

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to

put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, results of operations and financial condition.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debatement, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We will need to develop 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, 2020, we had 141 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 \$1.38 and as high as \$12.98 during 2020. During this same period, our ordinary share prices have ranged from as low as €2.40 to as high as €23.52. 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 ongoing COVID-19 pandemic.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

As of December 31, 2020, our executive officers, directors, current 5% or greater shareholders and affiliated entities, including entities affiliated with Caisse de Dépôts et Consignations, entities affiliated with Baker Bros. Advisors LP, entities affiliated with Perceptive Advisors LLC, and entities affiliated with Boxer Capital, LLC together beneficially own approximately 44.8 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 the 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. On January 14, 2021, we received a notice from the Nasdaq Stock Market indicating that, since 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, Nasdaq had determined that we do not meet Nasdaq's quorum requirement under Listing Rule 5620(c)(i), or the Nasdaq Quorum Requirement. Prior to January 1, 2020, we were a foreign private issuer and was exempt, pursuant to Listing Rule 5615(a)(3), from complying with the Nasdaq Quorum Requirement. 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.

We have engaged in discussions with Nasdaq regarding our inability to comply simultaneously with the Nasdaq Quorum Requirement and applicable French laws and regulations. On December 31, 2020, as a result of these discussions, Nasdaq filed with the SEC a proposed rule change that would modify the Nasdaq Quorum Requirement applicable to a company incorporated outside of the United States where such company's home country law is in direct conflict with the Nasdaq Quorum Requirement. We believe such rule change, if approved by the SEC, will enable us to regain compliance with all applicable Listing Rules. However, there can be no assurance either that the SEC will approve the rule change submitted by Nasdaq or that we will be able to comply with the Quorum Requirement if the SEC does not approve the rule change submitted by Nasdaq.

In the event that our ADSs are delisted from Nasdaq and is 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.

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, 2020, 54,929,187 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 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 residents 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 a Member State of the European Union or in a state party to the EEA Agreement, including from the main French Stock Exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors' broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can only be convened by our chairman or our managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions; however, this mode of participation (by way of videoconference or teleconference) does not

apply to the adoption of decisions taken for the closing of the accounts for the fiscal year, including the consolidated financial statements;

- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our by-laws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations;
- transfers of shares shall comply with applicable insider trading rules and regulations and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, the sections of the by-laws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by at least a two thirds majority vote of our shareholders present, represented by a proxy or voting by mail at the meeting.

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

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

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

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

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis, transferable during a period starting two days prior to the opening of the subscription period or, if that day is not a trading day, the preceding trading day; and ending two days prior to the closing of the subscription period or, if that day is not a trading day, the preceding trading day, unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, the ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depository 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 depository 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 depository is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

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

Your ADSs, which may be evidenced by ADRs, are transferable on the books of the depository. However, the depository 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 depository may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository 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 depository 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.

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

Certain members of our board of directors and senior management, and those of our subsidiary, are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court

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

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

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

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

We are currently a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We will be a smaller reporting company and may take advantage of the scaled disclosures available to smaller reporting companies for so long as (i) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter or (ii) (a) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and (b) the market value of our voting and non-voting ordinary shares held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

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

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

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

U.S. Holders Of ADSs 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 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 assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. Based on the composition of our gross income and gross assets for our 2020 taxable year, we believe that we were likely a PFIC for the taxable year ending December 31, 2020, and we are not able to provide any assurance as to whether we will, or will not be classified as a PFIC for the taxable year ending December 31, 2021. 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, 2020 are accurate 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 we are a PFIC for any taxable year during which a U.S. Holder (as defined below) holds ADSs, a U.S. Holder may be subject to adverse tax consequences if a mark-to-market election or a qualified electing fund, or QEF, election has not been made with respect to its ADSs. A U.S. Holder may incur significant additional U.S. federal income taxes on income resulting from certain distributions on, or any gain from the disposition of, such ADSs, as such income generally would be allocated over the U.S. Holder’s holding period for its ADSs. The amount allocated to the current taxable year (*i.e.*, the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC would be subject to tax as ordinary income earned in the current year, and all other amounts would be subject to tax at the highest rates of U.S. federal income taxation in effect for such years, with an interest charge then imposed on the resulting taxes in respect of such income. Furthermore, if we are a PFIC for any taxable year during which the U.S. Holder holds ADSs, dividends paid by us would not be eligible for preferential individual rates of U.S. federal income tax. In addition, U.S. Holders that own an interest in a PFIC are required to comply with certain reporting requirements.

A U.S. Holder may in certain circumstances mitigate the adverse tax consequences of the PFIC rules by filing an election to treat the PFIC as a QEF, or, if shares of the PFIC are “marketable stock” for purposes of the PFIC rules, by making a mark-to-market election with respect to the shares of the PFIC.

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

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,470 square meter facility consisting of office and laboratory space, pursuant to a lease agreement dated March 3, 2015, which expires on March 8, 2024. We entered into an additional lease for offices in Montrouge, France in July 2018. This facility consists of 1,808 square meters of office space, pursuant to a lease agreement dated July 1, 2018, which initially expires on June 30, 2027. In December 2020, in light of our global restructuring, we notified the landlord of our intention to terminate the lease for the additional office space as of June 30, 2021.

We also have two facilities in Bagneux, France. These facilities consist of 2,237 square meters of office and laboratory space and are used primarily by our industrial and production teams. One of the facilities is our pharmaceutical manufacturing establishment, which is focused on the quality control of our manufactured therapeutic patches. In April 2018, we entered into an addendum to our lease for an additional 500 square meters of office space in building B of Green Square, Bagneux, France. These facilities are leased under one agreement, which initially expires on May 31, 2030. In December 2020, we notified the landlord of our intention to terminate the lease agreement for both spaces as of August 31, 2021.

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 and expires on February 25, 2023. In light of our global restructuring, the current stage of regulatory interactions regarding Viaskin Peanut, and the ongoing COVID-19 pandemic, we are currently seeking to sublease this office space, subject to landlord consent.

In September 2016, we entered into a lease for a commercial facility of 8,919 square feet in Summit, New Jersey, which is intended to support the launch and commercialization of Viaskin Peanut in North America, if the appropriate regulatory approvals are received. In July 2018, we entered into a lease for an additional 12,629 square feet in the same building and made both leases co-terminus on July 10, 2028. This lease includes extension options of two five-year periods. In light of our global restructuring and the current stage of regulatory interactions regarding Viaskin Peanut, we are currently seeking to sublease the additional 12,629 square feet, subject to landlord consent.

We believe that our office, laboratory, and commercial spaces are sufficient to meet our current needs and that suitable additional space will be available if, as and when needed.

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. Other than as described below, we are not currently subject to any material legal proceedings.

Class Action Complaint

On January 15, 2019, Travis Ito-Stone individually and on behalf of all others similarly situated, filed a class action complaint for violation of federal securities laws against us, our former Chief Executive Officer, our current Chief Executive Officer, our former Deputy Chief Executive Officer and our former Chief Business Officer in the United States District Court for the District of New Jersey. Subsequently, Ruth Pruitt and Asdrubal Delgado were appointed as lead plaintiffs and an amended complaint was filed on January 24, 2020 and a second amended complaint was filed on June 5, 2020. The complaint, as amended, purports to bring a federal securities class action on behalf of a class of persons who acquired our securities between February 14, 2018 and March 16, 2020 and seeks to recover damages caused by defendants' alleged violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 10b-5 promulgated thereunder. The complaint alleges, among other things, that the defendants made materially false and/or misleading statements related to our business, operational and compliance policies. The plaintiff seeks, among other things, certification of a class, an award of unspecified compensatory damages, interest, costs and expenses, including counsel fees and expert fees, and other relief as the court deems appropriate.

We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. We cannot predict at this point the length of time that this action will be ongoing or the liability, if any, which may arise therefrom.

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 March 15, 2021, there were approximately 209 holders of record of our ordinary shares and 1 holder 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.

Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2020, we issued the following unregistered securities:

- On January 15, 2020, the issuances of ordinary shares following the exercise 24,990 employee warrants and the exercise of 35,000 employee's stock options;
- On November 25, 2020, the issuance of 2,000 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 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. Selected Financial Data.

Because we are considered to be a "smaller reporting company" under SEC rules and regulations, we are not required to provide the information required by this item in this Annual Report.

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 EPITM, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin. We have generated significant data demonstrating that Viaskin's mechanism of action is novel and differentiated, as it 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 patients, including infants and 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.

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.

Following receipt of a Complete Response Letter, or CRL, from the U.S. Food and Drug Administration, or FDA, in connection with our Biologics License Application, or BLA, for Viaskin™ Peanut, beginning in August 2020, we scaled down our other clinical programs and pre-clinical spend to focus on Viaskin Peanut. We also initiated a global restructuring plan in June 2020 to provide operational latitude to progress the clinical development and regulatory review of Viaskin™ Peanut in the United States and European Union. Based on guidance received from the FDA in January 2021, that we plan to implement, and expected cost savings from implementation of the global restructuring plan, we expect that our current balance of cash and cash equivalents of \$196.4 million as of December 31, 2020 will be sufficient to fund our operations to the second half of 2022.

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. As a result of disruptions to the global financial markets as a result of the ongoing COVID-19 pandemic, 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. The ongoing COVID-19 pandemic has 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 and on acceptable terms, if at all.

We have initiated a global restructuring plan in June 2020 to provide operational latitude to progress in the clinical development and regulatory review of investigational Viaskin™ Peanut in the United States and European Union. The full implementation of the restructuring plan will result in a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals dedicated to the pursuit of innovation and scientific development of novel therapies. We expect full implementation of the organization-wide costs reduction measures to be completed by the second half of 2021. We expect to continue to incur significant expenses and

increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our research, pre-clinical and clinical development of our product candidates, including expanding the scope of our trials for Viaskin Peanut;
- seek regulatory and marketing approvals and pursue commercial activities for Viaskin Peanut, especially in North America and in the European Union;
- seek regulatory and marketing approvals for our other product candidates that successfully complete clinical trials;
- continue to establish a sales, marketing and distribution infrastructure to commercialize Viaskin Peanut, if approved, and any other products for which we may obtain marketing approval, especially in North America and in the European Union;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- initiate and conduct any post-approval clinical trials, if required by the FDA or by the EMA, for our approved products, if any;
- initiate additional pre-clinical, clinical or other studies for our product candidates;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- reach 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; and
- impacts of the ongoing COVID-19 pandemic;
- 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.

Components of Our Results of Operations

Operating Income

Our operating income consists of other income, as we generated no revenue from our operating activities in 2019 or 2020.

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/middle size company, immediate payment of the Research Tax Credit can be requested. Since the beginning in the fiscal year ending December 31, 2019, we no longer benefit from the immediate reimbursement of the Research Tax Credit due to the loss of the Small and Medium-sized Enterprises (SMEs) status under EU law. The Research Tax Credit will now be refunded three years after the tax declaration in the event we cannot offset it against corporate income tax due.

The repayable portion of the Research Tax Credit in more than one year is recorded in other non-current assets

Collaboration agreement with Nestlé Health Science

On May 31, 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAGIC, 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 MAGIC up through a pivotal Phase III clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAGIC 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.

In 2020, the ongoing COVID-19 pandemic impacted our current clinical trials, including the Phase II clinical trial conducted as part of the development activities pursuant to the collaboration and license agreement with Nestlé Health Science. We experienced a decrease in new patients enrolling in this Phase II clinical trial and modified the protocols of the clinical trial. As a result of these delays, we expect to incur additional clinical and production costs related to the Phase II clinical trial.

Accordingly, as of December 31, 2020, we updated our measurement of progress of the PII conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. We have recorded an accrual in the amount of the excess between our current best estimates of costs yet to be incurred and incomes yet to be recognized for the completion of the PII.

Operating Expenses

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

Research and Development

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

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

Our direct research and development expenses consist principally of external costs, such as startup fees paid to investigators, consultants, central laboratories, and CROs in connection with our clinical trials, and costs related to acquiring and manufacturing clinical study materials. We do not allocate personnel-related costs, costs associated with our general platform improvements, depreciation or other indirect costs to specific programs, as they are deployed across multiple projects under development and, as such, are separately classified as personnel and other expenses.

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

In the year ended December 31, 2020, we spent \$101.6 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, 2020 and 2019, respectively:

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Research and development expenses related to Viaskin Peanut(1)	\$ 70,507	\$ 73,526
As a percentage of research and development expenses, excluding share-based compensation expense	69%	69%
Research and development expenses related to Viaskin Milk(1)	\$ 4,750	\$ 8,117
As a percentage of research and development expenses excluding share-based compensation expense	5%	8%
Other research and development expenses(1)	\$ 26,966	\$ 24,872
Total research and development expenses, excluding share-based compensation expense	\$ 102,222	\$ 106,516
Share-based compensation expenses included in research and development expenses	\$ (616)	\$ 8,588
Total research and development expenses	\$101,607	\$115,103

(1) Excludes employee share-based compensation expense.

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

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

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

Sales and Marketing

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

General and Administrative

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

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

Restructuring Costs

We initiated a global restructuring plan in June 2020 to provide operational latitude to progress in the clinical development and regulatory review of investigational Viaskin™ Peanut in the United States and European Union. We expect full implementation of the restructuring plan to result in a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals dedicated to the pursuit of innovation and scientific development of novel therapies. We expect full implementation of the organization-wide costs reduction measures to be completed by the second half of 2021.

The restructuring costs, which were \$23.6 million as of December 31, 2020, are mainly comprised of payroll expenses, restructuring-related consulting and legal fees, as well as impairment of facilities and right of use assets following resizing of facilities.

Finance Income (Expense)

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

Results of Operations

The following table summarizes our results of operations; derived from our consolidated financial statements, have been prepared in compliance with generally accepted accounting principles in the United States, or U.S. GAAP, and presented in thousands of U.S. Dollars for the years ended December 31, 2020 and 2019:

	December 31,	
	2020	2019
<i>(Amounts in thousands of U.S. Dollars)</i>		
Operating income	\$ 11,276	\$ 14,708
Operating expenses :		
Research and development expenses	(101,607)	(115,103)
Sales & marketing expenses	(9,879)	(21,560)
General & administrative expenses	(35,081)	(49,068)
Restructuring expenses	(23,552)	—
Total Operating expenses	(170,118)	(185,731)
Financial expenses	(724)	(378)
Income tax	10	(610)
Net loss	<u>\$(159,555)</u>	<u>\$(172,011)</u>
Basic/diluted Net loss per share attributable to shareholders	\$ (2.95)	\$ (4.65)

Comparison of the Years Ended December 31, 2020 and 2019

Operating Income

We generated operating income of \$11.3 million in 2020 compared to \$14.7 million in 2019, a decrease of 23.3%. This income was mainly generated from the French research tax credit (*crédit d'impôt recherche*), or CIR, and by revenue recognized under our collaboration agreement with Nestlé Health Science.

	Year Ended December 31,	
	2020	2019
<i>(Amounts in thousands of U.S. Dollars)</i>		
Sales	—	—
Other income	11,276	14,708
<i>Research tax credit</i>	9,930	10,937
<i>Other operating income</i>	1,346	3,771
Total operating income	11,276	14,708

In 2020, we recognized income of \$1.3 million under our collaboration with Nestlé Health Science. On May 31, 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAGIC, a ready-to-use and standardized atopy patch test tool for the diagnosis of 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 MAGIC up through a pivotal Phase III clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAGIC 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.

In 2020, the ongoing COVID-19 pandemic impacted our current clinical trials, including the Phase II clinical trial ("PII") conducted as part of the development activities pursuant to the collaboration and

license agreement with Nestlé Health Science. We experienced a decrease in new patients enrolling in this Phase II clinical trial and modified the protocols of the clinical trial. As a result of these delays, we expect to incur additional clinical and production costs related to the Phase II clinical trial.

Accordingly, as of December 31, 2020, we updated our measurement of progress of the PII conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. We have recorded an accrual in the amount of the excess between our current best estimates of costs yet to be incurred and income yet to be recognized for the completion of the PII.

Operating Expenses

Restructuring costs are presented as a separate line item in the Statement of Operations as of December 31, 2020. We have also updated our assumptions to take into account a delay in timelines for regulatory approval of Viaskin Peanut impacts arising from the restructuring.

Research and Development expenses

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

<i>(Amounts in thousands of U.S. Dollars)</i>	December 31	
	2020	2019
Personnel expenses	25,703	47,571
Sub-contracting, Collaboration, and Consultants	48,721	53,455
Depreciation and amortization	16,714	2,862
Rental	3,977	4,321
Small equipment and other supplies	2,586	3,150
Conferences and travel expenses	1,055	1,876
Others	2,851	1,869
Total Research and Development expenses	101,607	115,103

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 expense decreased by \$13.5 million or 11.7% in the year ended December 31, 2020 compared to the year ended December 31, 2019, primarily due to a decrease of 46% in personnel expenses in 2020 compared to 2019, which decrease reflects reduced bonuses, employee retention measures and share-based compensation expenses, directly related to the decrease in the average workforce as we completed our global restructuring plan. The average workforce dedicated to Research and Development decreased in comparison to 2019 (from 215 employees in 2019 to 186 employees in 2020).

Decrease in research and development expense is also due to a decrease of 8.9% in sub-contracting, collaborations and consultants mainly due to the budget discipline measures and COVID-19 effects partially offset by an increase in depreciation and amortization driven by inventory depreciation and accelerated depreciation of PP&E linked with the early termination of several leases pursuant to restructuring.

Sales and Marketing Expenses

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

<i>(Amounts in thousands of U.S. Dollars)</i>	December 31	
	2020	2019
Personnel expenses	5,217	14,231
Fees	3,216	4,695
Rental	722	712
Marketing, tradeshow and travel expenses	790	1,500
Depreciation and amortization	(165)	290
Others	99	132
Total Sales & Marketing expenses	9,879	21,560

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

Sales and marketing expense decreased by \$11.7 million, or 54.2% in 2020 compared to 2019, primarily due to a decrease in personnel expenses by 63.3% compared to 2019, including bonuses, employee retention measures and share-based compensation expenses, directly related to the decrease in the average workforce as we completed our global restructuring plan. The average workforce dedicated to sales and marketing decreased in comparison to 2019 (from 35 employees in 2019 to 22 employees in 2020).

Decrease on sales and marketing expenses is also due to decrease of \$2.2 million in fees and marketing in line with budget discipline exercised and the impacts of the ongoing COVID-19 pandemic on tradeshow and travel expenses.

General and Administrative Expenses

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

<i>(Amounts in thousands of U.S. Dollars)</i>	December 31	
	2020	2019
Personnel expenses	9,906	28,079
Fees	12,684	12,183
Rental	1,064	849
Insurance policies	6,061	3,045
Corporate communication and travel expenses	272	1,089
Depreciation and amortization	943	(103)
Others	4,153	3,925
Total General & Administrative expenses	35,081	49,068

General and administrative expenses were \$35.1 million in 2020, compared to \$49.1 million in 2019, or a decrease of 28.5%.

General and administrative expenses decreased by \$14.0 million or 28.5% in 2020 compared to 2019, primarily due to decreased in personnel expenses by 64.7% compared to 2019, including bonuses, employee retention measures and share-based compensation expenses, directly related to the decrease in the average workforce as we completed our global restructuring plan. The average workforce dedicated to general and administrative expenses decreased in comparison to 2019 (from 69 employees in 2019 to 63 employees in 2020)

Insurance policies increased by \$3.0 million and mainly relates to the increase in Directors and Officers insurance premium.

Restructuring

The following table summarizes restructuring costs as of December 31, 2020 included in the statement of operations:

	December 31,	
	2020	2019
<i>(Amounts in thousands of U.S. Dollars)</i>		
Employee-related expenses	19,194	—
Effects of restructuring on leases	2,028	—
Other restructuring costs	2,330	—
Total restructuring costs	<u>23,552</u>	<u>—</u>

We initiated a global restructuring plan in June 2020 to provide operational latitude to progress in the clinical development and regulatory review of investigational Viaskin™ Peanut in the United States and European Union. We expect full implementation of the restructuring plan to result in a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals dedicated to the pursuit of innovation and scientific development of novel therapies. We expect full implementation of the organization-wide costs reduction measures to be completed by the second half of 2021.

The restructuring costs of \$23.6 million as of December 31, 2020 are mainly comprised of payroll expenses, restructuring-related consulting and legal fees, as well as impairment of facilities and right of use assets following resizing of facilities.

The following table summarizes restructuring flows as of December 31, 2020 included in current provisions and other current liabilities on the statement of consolidated financial position:

	Restructuring
	liabilities
<i>(Amounts in thousands of U.S. Dollars)</i>	
Restructuring liability - January 1, 2020	—
Restructuring costs	23,552
Restructuring costs – non-cash items	(2,028)
Amounts paid	(12,137)
Restructuring liability - December 31, 2020	<u>9,387</u>
<i>of which current provisions</i>	<i>1,993</i>
<i>of which other current liabilities</i>	<i>7,394</i>

Financial loss

Our financial loss was \$0.7 million in 2020, compared to a loss of \$0.4 million in 2019. This item includes the financial revenues on our financial assets and foreign exchange losses.

Liquidity and Capital Resources

The table below summarizes our sources and uses of cash for the years ended December 31, 2020 and 2019.

	Year Ended December 31,	
	2020	2019
	(in thousands of U.S. Dollars)	
Net cash flow used in operating activities	(165,607)	(148,347)
Net cash flow used in investing activities	(2,865)	(5,662)
Net cash flow provided by financing activities	149,548	207,578
Effect of exchange rate changes on cash and cash equivalents	22,022	(886)
Net increase (decrease) in cash and cash equivalents	3,097	52,683

Operating Activities

Our net cash flows used in operating activities were \$165.6 million and \$148.3 million in 2020 and 2019 respectively. Our net cash flows used in operating activities increased by \$17.3 million mainly due to restructuring cash out and effect of Research Tax Credit as it will now be refunded three years after the tax declaration.

Investing Activities

Our net cash flows used in investing activities were \$2.9 million and \$5.7 million in 2020 and 2019 respectively. Those investments 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 decreased to \$149.5 million in 2020 from \$207.6 million in 2019. Financing activities consisted mainly of our underwritten global offerings in 2019 and in 2020.

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, 2020, 112,302 shares and \$0.3 million were in the liquidity account. The liquidity agreement has a term of one year and will renew automatically unless otherwise terminated by either party.

Cash and Funding Sources

During 2019 and 2020, 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
	(thousands of U.S. Dollars)			
2019	206,766	—	—	208,766
2020	150,010	—	—	150,010
Total	358,776	—	—	358,776

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.

Capital Expenditures

As all the clinical research and development expenditures are expensed until marketing authorizations are obtained, the principal investments made over 2019 and 2020 have been related primarily to the industrial machinery and equipment, which are expected to be commissioned in order to support the commercialization of Viaskin Peanut, if approved and, secondarily, to the acquisition of computer and office equipment.

Funding Requirements

On December 31, 2020, we had \$196.4 million in cash and cash equivalents compared to \$193.3 million of cash and cash equivalents on December 31, 2019. We have incurred operating losses and negative cash flows from operations since our inception. Net cash used for operating activities was respectively \$165.6 and \$148.4 million for the years 2020 and 2019. As of December 31, 2020, we recorded a net loss of \$159.6 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 French administration on research tax credits (Crédit 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.

Following receipt of a CRL from the FDA in connection with our BLA for Viaskin Peanut, beginning in August 2020, we scaled down our other clinical programs and pre-clinical spend to focus on Viaskin Peanut. We also initiated a global restructuring plan in June 2020 to provide operational latitude to progress the clinical development and regulatory review of Viaskin Peanut in the United States and European Union. Based on guidance received from the FDA in January 2021, that we plan to implement, and expected cost savings from implementation of the global restructuring plan, we expect that our current balance of cash and cash equivalents of \$196.4 million as of December 31, 2020 will be sufficient to fund our operations to the second half of 2022.

We intend to seek additional capital as it prepares for the launch of Viaskin Peanut, if approved, and continues other research and development efforts. We may seek to finance its future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings. As a result of disruptions to the global financial markets as a result of the ongoing COVID-19 pandemic, 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. The ongoing COVID-19 pandemic has 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 for us, including reduced ability to raise additional capital when needed and on acceptable terms, if at all.

Our financial statements have been prepared on a going concern basis as of December 31, 2020.

Contractual Obligations and Commitments

The following table discloses aggregate information about material contractual obligations and periods in which payments were due as of December 31, 2020. Future events could cause actual payments to differ from these estimates.

	Less than One year	1 to 3 years	3 to 5 years	More than 5 years	Total
	(Amounts in thousands of U.S. dollars)				
Conditional advances	724	543	—	—	1,267
Operating leases	3,708	5,978	2,729	1,790	14,205
Purchase obligations - Obligations Under the Terms of CRO Agreements	21,677	23,615	—	—	45,292
Total	26,110	30,136	2,729	1,790	60,764

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.

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,470 square meter facility consisting of office and laboratory space, pursuant to a lease agreement dated March 3, 2015, which expires on March 8, 2024. We entered into an additional lease for offices in Montrouge, France in July 2018. This facility consists of 1,808 square meters of office space, pursuant to a lease agreement dated July 1, 2018, which initially expires on June 30, 2027. In December 2020, in light of our global restructuring, we notified the landlord of our intention to terminate the lease for the additional office space as of June 30, 2021.

We also have two facilities in Bagneux, France. These facilities consist of 2,237 square meters of office and laboratory space and are used primarily by our industrial and production teams. One of the facilities is our pharmaceutical manufacturing establishment, which is focused on the quality control of our manufactured therapeutic patches. In April 2018, we entered into an addendum to our lease for an additional 500 square meters of office space in building B of Green Square, Bagneux, France. These facilities are leased under one agreement, which initially expires on May 31, 2030. In December 2020, we notified the landlord of our intention to terminate the lease agreement for both spaces as of August 31, 2021.

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 and expires on February 25, 2023. In light of our global restructuring, the current stage of regulatory interactions regarding Viaskin Peanut, and the ongoing COVID-19 pandemic, we are currently seeking to sublease this office space, subject to landlord consent. In September 2016, we entered into a lease for a commercial facility of 8,919 square feet in Summit, New Jersey, which is intended to support the launch and commercialization of Viaskin Peanut in North America, if the appropriate regulatory approvals are received. In July 2018, we entered into a lease for an additional 12,629 square feet in the same building and made both leases co-terminus on July 10, 2028. This lease includes extension options of two five-year periods. In light of our global restructuring and the current stage of regulatory interactions regarding Viaskin Peanut, we are currently seeking to sublease the additional 12,629 square feet, subject to landlord consent.

In connection with the launch of our clinical trials for Viaskin Peanut and Viaskin Milk, we signed agreements with several contract research organizations. Expenses associated with the ongoing trials amounted globally to €175.0 million. As of December 31, 2020, the amount we are still obligated to pay in connection with these contracts through 2023 is \$45.3 million.

Critical Accounting Policies and Significant Judgments and Estimates

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

Revenue Recognition - Collaboration agreement with Nestlé Health Science

On May 31, 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAGIC, 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 MAGIC up through a pivotal Phase III clinical program, and if appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAGIC 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.

In 2020, the ongoing COVID-19 pandemic impacted our current clinical trials, including the Phase II ("PII") clinical trial conducted as part of the development activities pursuant to the collaboration and license agreement with Nestlé Health Science. We experienced a decrease in new patients enrolling in this Phase II clinical trial and modified the protocols of the clinical trial. As a result of these delays, we expect to incur additional clinical and production costs related to the Phase II clinical trial.

Accordingly, as of December 31, 2020, we updated our measurement of progress of the PII conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. We have recorded an accrual in the amount of the excess between our current best estimates of costs yet to be incurred and income yet to be recognized for the completion of the PII.

Share-Based Compensation

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

Determining the fair value of the share-based payments at the grant date requires judgment. We calculated the fair value of stock options on the grant date using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly subjective assumptions, including the expected volatility, expected term, risk-free interest rate and dividend yield.

Exercise price

The exercise price of our stock options is based on the fair market value of our ordinary shares.

Risk-free interest rate

The risk-free interest rate is based on French government bonds (GFRN) with a maturity corresponding to the maturity of the share options.

Expected term

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

Expected Volatility

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

Expected Dividend yield

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

In the following table, the weighted average fair value of underlying shares are provided in euros, as we are incorporated in France and the euro is the currency used for the grants.

We estimated the following assumptions for the calculation of the fair value of our stock options:

Stock options per grant date	Assumptions per years ended, December 31,	
	2019	2020
Weighted average fair value of underlying shares in €*	15.26	5.54
Weighted average expected volatility	70.8%	87.3%
Weighted average risk-free interest rate	(0.1)%	(0.5)%
Weighted average expected term (in years)	6.0	6.0
Dividend yield	0	0

* 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.

Smaller Reporting Company Status

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

Off-balance Sheet Arrangements

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.

Interest Rate Risk

We seek to engage in prudent management of our cash and cash equivalents, mainly cash on hand and common financial instruments (typically short- and mid-term deposits). Furthermore, the interest rate risk related to cash, cash equivalents and common financial instruments is not significant based on the quality of the financial institutions with which we work.

Liquidity Risk

On December 31, 2020, we have \$196.4 million in cash and cash equivalents compared to \$193.3 million of cash and cash equivalents on December 31, 2019. We have incurred operating losses and negative cash flows from operations since our inception. Net cash used for operating activities was respectively \$165.6 and \$148.4 million for the years 2020 and 2019. As of December 31, 2020, we recorded a net loss of \$159.6 million.

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The financial statements have been prepared on a going concern basis as of December 31, 2020.

Foreign currency exchange rate risk

The Consolidated Financial Statements are presented in U.S. dollars, which differs from the functional currency of DBV Technologies S.A., which is the Euro. The statements of financial position of consolidated entities having a functional currency different from the presentation currency are translated at the closing exchange rate (spot exchange rate at the statement of financial position date) and the statements of operations, statements of comprehensive income (loss) and statements of cash flow of such consolidated entities are translated at the average period to date exchange rate. The resulting translation adjustments are included in equity under the caption "Accumulated other comprehensive gain (loss)" in the Consolidated Statements of Changes in Shareholders' Equity.

We are exposed to foreign exchange risk inherent in some of our supplies obtained in the United States, which have been invoiced in dollars. As of this date, we do not have revenues in dollars nor in any other currency. Due to the relatively low level of these expenditures, we believe our exposure to foreign exchange risk is unlikely to have a material adverse impact on our results of operations or financial position. Our exposure to currencies other than the dollar is negligible. We plan to adopt a hedging policy to minimize the impact of currency fluctuations on our financial results. As a result, we intend to use hedging derivatives to reduce our exposure to foreign exchange risk. These instruments will be intended either to cover foreign currency debts and trade receivables, or to cover highly likely budgetary exposures and/or firm commitments. At this time, we have not put in place any hedging instruments.

We are also exposed foreign currency exchange rate fluctuations in our consolidated financial statements. The foreign currency transactions are converted to functional currency of the entity at the rate of exchange applicable on the transaction date. At period-end, foreign currency monetary assets and liabilities are converted at the rate of exchange prevailing on that date. The resulting exchange gains or losses are recorded in the entity individual statements of operations in "Other financial income (expense)" with the exception of exchange differences arising from monetary items that form part of the reporting entity's net investment in a foreign operation which are recognized in other comprehensive income (loss); they will be recognized in profit or loss on disposal of the net investment.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

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, 2020, 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, 2020.

Changes in Internal Control over Financial Reporting.

Following our global restructuring plan initiated in June 2020 (consisting of a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals) and potential associated disputes, our management has implemented incremental procedures and internal controls surrounding the review of our legal and contractual obligations towards our employees and their resulting accounting impacts. In particular, management implemented a control with respect to the share-based plans consisting in the cross-functional and external legal review of each grant's supporting documentation to secure consistent understanding of the vesting conditions with management decision or intention and ensure that the vesting conditions as described in the plans supporting documentation and agreed by both Company and employee are correctly applied for the evaluation and recording of the share-based payment expense. This incremental control identified necessary adjustments, as described in Footnote 1 in the Notes to the Consolidated Financial Statements. This specific control, the absence of which would have been considered as a material weakness as of December 31, 2020, has been considered as effective as of December 31, 2020.

Except for the changes described above, there were no changes to our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in the sections titled "Board of Directors and Corporate Governance" and "Information About Our Executive Officers" in our Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in the sections titled "Executive Compensation" 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 Plan Information” 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 “Transactions with Related Persons” 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 “Independent Registered Public Account Firm Fees” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

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

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

EXHIBIT INDEX

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
3.1*	By-laws (<i>statuts</i>) of the registrant (English translation)				
4.1	Form of Deposit Agreement	Form F-1/A	333-198870	4.1	10/15/14
4.2	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
4.4	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
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
10.2	Commercial Lease between the registrant and SELECTINVEST 1, dated April 28, 2011 (English translation)	Form F-1	333-198870	10.1	09/22/14
10.3	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
10.4#	Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016	Form 20-F	001-36697	4.14	03/22/17
10.5#	Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 2018	Form 20-F	001-36697	4.5	04/01/19
10.6†	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
10.7†	2013 and 2014 Share Option Plans (English translation)	Form F-1	333-198870	10.4	09/22/14
10.8†	2012, 2013 and 2014 Free Share Plans (English translation)	Form F-1	333-198870	10.5	09/22/14
10.9†	Summary of BSA	Form F-1	333-198870	10.6	09/22/14
10.10†	Summary of BSPCE	Form F-1	333-198870	10.7	09/22/14
10.11†	2015 Share Option Plan (English translation)	Form 20-F	001-36697	4.10	04/28/16
10.12†	2015 Free Share Plans (English translation)	Form 20-F	001-36697	4.11	04/28/16
10.13†	2016 Share Option Plan (English translation)	Form 20-F	001-36697	4.12	03/22/17
10.14†	2016 Free Share Plan (English translation)	Form 20-F	001-36697	4.13	03/22/17
10.15†	2017 Share Option Plan (English translation)	Form 20-F	001-36697	4.14	03/16/18

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
10.16†	2017 Free Share Plan (English translation)	Form 20-F	001-36697	4.15	03/16/18
10.17†	2018 Share Option Plan (English translation)	Form 20-F	001-36697	4.17	04/01/19
10.18†	2018 Free Share Plan (English translation)	Form 20-F	001-36697	4.18	04/01/19
10.19†	2019 Share Option Plan (English translation)	Form 20-F	001-36697	4.19	03/20/20
10.20†	2019 Free Share Plans (English translation)	Form 20-F	001-36697	4.20	03/20/20
10.21†*	2020 Stock Option Plan (English translation)				
10.22†*	2020 Free Share Plan (English translation)				
10.23†*	Executive Agreement, dated November 29, 2018, between the registrant and Daniel Tassé				
10.24†*	First Amendment to the Executive Agreement of Daniel Tassé, dated June 27, 2019, between the registrant and Daniel Tassé				
10.25†*	Executive Agreement, dated July 22, 2019, between the registrant and Pharis Mohideen				
10.26†*	Letter Agreement, dated June 26, 2019, between the registrant and Sébastien Robitaille (English translation)				
10.27*	Letter Agreement, dated December 1, 2020, between the registrant and Sébastien Robitaille (English translation)				
21.1	List of subsidiaries of the registrant	Form 20-F	001-36697	8.1	03/20/20
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) 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				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				

<u>Exhibit</u>	<u>Description</u>	<u>Incorporated by Reference</u>			
		<u>Schedule/ Form</u>	<u>File Number</u>	<u>Exhibit</u>	<u>File Date</u>
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DBV Technologies S.A.

/s/ Daniel Tassé

Name: Daniel Tassé

Title: Chief Executive Officer

(Principal Executive Officer)

Date: March 17, 2021

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities indicated on March 17, 2021.

<u>Signature</u>	<u>Title</u>
<u>/s/ Daniel Tassé</u> Daniel Tassé	Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Sebastián Robitaille</u> Sebastián Robitaille	Chief Financial Officer (Principal Financial and Accounting Officer)
<u>/s/ Torbjörn Bjerke</u> Torbjörn Bjerke	Director
<u>/s/ Michel de Rosen</u> Michel de Rosen	Director
<u>/s/ Mailys Ferrere</u> Mailys Ferrere	Director
<u>/s/ Claire Giraut</u> Claire Giraut	Director
<u>/s/ Michael J. Goller</u> Michael J. Goller	Director

Signature

Title

/s/ Viviane Monges Director
Viviane Monges

/s/ Julie O'Neil Director
Julie O'Neil

/s/ Daniel Soland Director
Daniel Soland

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<u>Consolidated Statements of Financial Position as of December 31, 2020 and 2019</u>	F-5
<u>Consolidated Statements of Operations for the Years Ended December 31, 2020 and 2019</u>	F-6
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<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019</u>	F-8
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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 statement of financial position of DBV Technologies S.A. and subsidiaries (the “Company”) as of December 31, 2020, and the related consolidated statements of operations, comprehensive loss, cash flows and changes in shareholders’ equity for the year ended December 31, 2020, 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, 2020, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Restricted stock units – Refer to Notes 1 and 14 to the consolidated financial statements

Critical Audit Matter Description

The Company grants restricted stock units to its employees. Certain awards granted contain performance conditions. The Company recognizes share-based payments compensation over the requisite service period based

on the grant-date fair value, and when applicable, based upon the likelihood of achieving the performance condition. The determination of the requisite service period and the estimate of awards that are expected to vest depends on the legal interpretation of the award agreements with employees under the French labor laws and related jurisprudence. Changes in interpretations could significantly impact the accounting for the share-based payments as related to restricted stock units.

We identified the evaluation of the accounting for share-based payments as related to restricted stock units as a critical audit matter because of the judgement required in the legal interpretation of the vesting conditions of the award agreements. This required a high degree of auditor judgment, including the need to involve legal professionals with specialized skills and knowledge when performing audit procedures to evaluate the reasonableness of management's accounting for share-based payments as related to restricted stock units.

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 obtained an understanding and tested the design and operating effectiveness of the internal control related to the legal interpretation of the restricted stock units award agreements.
- We evaluated, with the assistance of legal professionals with specialized skills and knowledge, the reasonableness of the judgments made by the Company in the legal interpretation of the vesting conditions of the award agreements by reading the restricted stock unit plans and the other governing documents, including the shareholders' meetings minutes and Board of directors minutes, for each award granted as related to restricted stock units to evaluate whether the relevant terms and conditions impacting the interpretation of the award agreements were appropriately considered by the Company.
- We evaluated the adequacy of the Company's disclosures relating to share-based payments as related to restricted stock units in the consolidated financial statements.

/s/ Deloitte & Associés

KPMG S.A.
/s/ Cédric Adens

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

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

Paris-La Défense, France
March 17, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statement of financial position of DBV Technologies S.A. and subsidiaries (the “Company”) as of December 31, 2019, and the related consolidated statements of operations, comprehensive loss, cash flows and changes in shareholders’ equity for the year ended December 31, 2019, 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, 2019, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm 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 audit 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.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Deloitte & Associés

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

Paris-La Défense, France

March 17, 2021

DBV Technologies S.A.
Consolidated Statements of Financial Position
(amounts in thousands, except share and per share data)

	Note	<u>Year ended December 31,</u>	
		<u>2020</u>	<u>2019</u>
Assets			
Current assets:			
Cash and cash equivalents	3	\$ 196,352	\$ 193,255
Trade receivables	4	2,230	—
Inventories and work in progress	5	—	2,289
Other current assets	6	8,792	9,006
Total current assets		207,375	204,550
Property, plant, and equipment, net	7	24,792	25,019
Right-of-use assets related to operating leases	8	10,104	23,586
Intangible assets		41	48
Other non-current assets	9	29,935	18,523
Total non-current assets		64,871	67,176
Total Assets		\$ 272,246	\$ 271,725
Liabilities and shareholder's equity			
Current liabilities			
Trade payables	10	\$ 20,338	\$ 24,004
Short-term operating leases	8	3,708	3,686
Short-term financial debt	11	724	648
Current contingencies	15	5,016	724
Other current liabilities	10	22,926	24,936
Total current liabilities		52,713	53,999
Long-term operating leases	8	10,496	21,995
Long-term financial debt	11	543	810
Non-current contingencies	15	2,527	1,656
Other non-current liabilities	11	475	80
Total non-current liabilities		14,042	24,541
Total liabilities		\$ 66,754	\$ 78,539
Shareholders' equity:			
Ordinary shares, €0.10 par value ; 54,929,187 and 47,028,510 shares authorized, and issued as at December 31, 2020 and 2019, respectively, and 4,036,263 and 4,026,688 shares outstanding as at December 31, 2020 and 2019, respectively		\$ 6,518	\$ 5,645
Additional paid-in capital		1,152,042	1,003,595
Treasury stock, 102,302 and 41,159 ordinary shares as of December 31, 2020 and 2019, respectively, at cost		(1,169)	(230)
Accumulated deficit		(958,543)	(798,987)
Accumulated other comprehensive income		484	108
Accumulated currency translation effect		6,158	(16,945)
Total shareholders' equity	13	\$ 205,491	\$ 193,186
Total liabilities and shareholder's equity		\$ 272,246	\$ 271,725

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

DBV Technologies S.A.
Consolidated Statements of Operations
(amounts in thousands, except share and per share data)

	Note	Year ended December 31,	
		2020	2019
Operating income	16	\$ 11,276	\$ 14,708
Operating expenses			
Research and development expenses	17	(101,607)	(115,103)
Sales & marketing expenses	17	(9,879)	(21,560)
General & administrative expenses	17	(35,081)	(49,068)
Restructuring expenses	2,17	(23,552)	—
Total Operating expenses		(170,118)	(185,731)
Loss from operations		(158,842)	(171,023)
Financial expenses		(724)	(378)
Loss before taxes		(159,566)	(171,401)
Income tax	18	10	(610)
Net loss		\$ (159,555)	\$ (172,011)
Basic/diluted Net loss per share attributable to shareholders	21	\$ (2.95)	\$ (4.65)
Weighted average number of shares outstanding used in computing per share amounts:	21	54,092,666	37,007,247

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

DBV Technologies S.A.
Consolidated Statements of Comprehensive Loss
(amounts in thousands)

	<u>Year Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Net loss	\$ (159,555)	\$ (172,011)
Foreign currency translation differences, net of taxes	23,104	(958)
Actuarial gains on employee benefits, net of taxes	376	585
Total comprehensive loss	<u>\$ (136,075)</u>	<u>\$ (172,384)</u>

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

DBV Technologies S.A.
Consolidated Statements of Cash Flows
(amounts in thousands)

	Notes	Year ended December 31,	
		2020	2019
Net loss for the period		\$(159,555)	\$(172,011)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation, amortization and accrued contingencies		10,461	2,595
Retirement pension obligations		(436)	515
Expenses related to share-based payments		(1,130)	17,239
Other elements		655	(134)
Changes in operating assets and liabilities:			
Decrease (increase) in inventories and work in progress		2,327	(527)
Decrease (increase) in trade receivables		(2,070)	34
Decrease (increase) in other current assets		(9,275)	3,194
(Decrease) increase in trade payables		(5,082)	(7,653)
(Decrease) increase in other current and non-current liabilities		(3,357)	8,398
Change in operating lease liabilities and right of use assets		1,854	3
Net cash flow used in operating activities		(165,607)	(148,347)
Cash flows used in investing activities:			
Acquisitions of property, plant, and equipment, net from proceeds		(2,732)	(5,567)
Acquisitions of intangible assets		(29)	(30)
Acquisitions of non-current financial assets		(103)	(65)
Net cash flows used in investing activities		(2,865)	(5,662)
Cash flows provided by financing activities:			
(Decrease) increase in conditional advances		(303)	(1,322)
Treasury shares		(563)	172
Capital increases, net of transaction costs		150,449	208,766
Other cash flows related to financing activities		(36)	(38)
Net cash flows provided by financing activities		149,548	207,578
Effect of exchange rate changes on cash and cash equivalents		22,022	(886)
Net (decrease) / increase in cash and cash equivalents		3,097	52,683
Net cash and cash equivalents at the beginning of the period		193,255	140,572
Net cash and cash equivalents at the end of the period	3	\$ 196,352	\$ 193,255

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

DBV Technologies S.A.
Consolidated Statements of Changes in Shareholders' Equity
(amounts in thousands, except share and per share data)

	<u>Ordinary shares</u>		Additional paid-in capital	Treasury stock	Acc. deficit	Acc. other comprehensive income (loss)	Acc. currency translation effect	Total Equity
	Number of Shares	Amount						
Balance at January 1, 2019	30,157,777	\$ 3,770	\$ 779,465	\$ (923)	\$(626,976)	\$ (477)	\$ (15,987)	\$ 138,872
Net (loss)	—	—	—	—	(172,011)	—	—	(172,011)
Other comprehensive income (loss)	—	—	—	—	—	585	(958)	(373)
Issuance of ordinary shares	16,870,733	1,875	206,891	—	—	—	—	208,766
Treasury shares	—	—	—	693	—	—	—	693
Share-based payments	—	—	17,239	—	—	—	—	17,239
Balance at December 31, 2019	47,028,510	5,645	1,003,595	(230)	(798,988)	108	(16,945)	193,186
Net (loss)	—	—	—	—	(159,555)	—	—	(159,555)
Other comprehensive income	—	—	—	—	—	376	23,104	23,480
Issuance of ordinary shares	7,900,677	873	149,576	—	—	—	—	150,449
Treasury shares	—	—	—	(939)	—	—	—	(939)
Share-based payments	—	—	(1,130)	—	—	—	—	(1,130)
Balance at December 31, 2020	54,929,187	\$ 6,518	\$ 1,152,042	\$ (1,169)	\$(958,543)	\$ 484	\$ 6,158	\$ 205,491

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

Note 1: Nature of the business and principles and accounting methods

Incorporated in 2002 under the laws of France, DBV Technologies S.A. (“DBV Technologies,” or the “Company”, or “we”, or the “group”) is a clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin™. The Company’s therapeutic approach is based on epicutaneous immunotherapy, or EPIT™, a proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin™.

Basis of Presentation

The Company’s consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the U.S. (“U.S. GAAP”) and presented in thousands of U.S. Dollars. Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”). We also follow the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). The Consolidated Financial Statements have been prepared assuming the Company will continue as a going concern and using the historical cost principle with the exception of certain assets and liabilities that are measured at fair value in accordance with U.S. GAAP. The categories concerned are detailed in the following notes.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated.

The following list presents all entities included in the consolidation scope for the year ended December 31, 2019 and 2020, as well as their country of incorporation and the percentage of ownership interests:

- DBV Technologies Inc. was incorporated in Delaware on April 7, 2014 (the “US subsidiary”). The share capital of this US subsidiary is 100% owned by DBV Technologies S.A. (“DBV Technologies”).
- DBV Australia Pty Ltd. was incorporated in New South Wales, Australia on July 3, 2018 (the “Australian subsidiary”). The share capital of this Australian subsidiary is 100% owned by DBV Technologies S.A. (“DBV Technologies”).
- DBV Canada Ltd. was incorporated in Ottawa, Ontario on August 13, 2018 (the “Canadian subsidiary”). The share capital of this Canadian subsidiary is 100% owned by DBV Technologies S.A. (“DBV Technologies”).
- DBV Pharma was incorporated in Paris on December 21, 2018 (the “French subsidiary”). The share capital of this French subsidiary is 100% owned by DBV Technologies S.A. (“DBV Technologies”).

Functional Currency and Translation of Financial Statements in Foreign Currency

The Consolidated Financial Statements are presented in U.S. dollars, which differs from the functional currency of the Company, being the Euro. The statements of financial position of consolidated entities having a functional currency different from the presentation currency are translated at the closing exchange rate (spot exchange rate at the statement of financial position date) and the statements of operations, statements of comprehensive loss and statements of cash flow of such consolidated entities are translated at the weighted average exchange rate. The resulting translation adjustments are included in equity under the caption “Accumulated other comprehensive income (loss)” in the Consolidated Statements of Changes in Shareholders’ Equity.

Conversion of Foreign Currency Transactions

Foreign currency transactions are converted to functional currency of the entity at the rate of exchange applicable on the transaction date. At period-end, foreign currency monetary assets and liabilities are converted at the rate of exchange prevailing on that date. The resulting exchange gains or losses are recorded in the entity individual statements of operations in “Financial income (expense)”; they will be recognized in profit or loss on disposal of the net investment.

Use of estimates

The preparation of the Company’s Consolidated Financial Statements requires the use of estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, and disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of income and expenses during the period. The Company bases its estimates and assumptions on historical experience and other factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. The actual results may differ from these estimates.

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

Going concern

Since its inception, the Company has primarily funded its operations with equity financings, and, to a lesser extent, public assistance aimed at supporting innovation and payments associated with research tax credits (Crédit d’Impôt Recherche). The Company does not generate product revenue and continues to prepare for the potential launch of its first product in the United States and in the European Union, if approved.

Following receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in connection with its Biologics License Application (BLA) for Viaskin™ Peanut, beginning in August 2020, the Company scaled down its other clinical programs and pre-clinical spend to focus on Viaskin™ Peanut. The Company also initiated a global restructuring plan in June 2020 to provide operational latitude to progress the clinical development and regulatory review of Viaskin™ Peanut in the United States and European Union. Based on guidance received from the FDA in January 2021, the Company’s plans to implement such guidance, and expected cost savings from implementation of the global restructuring plan, the Company expects that its current balance of cash and cash equivalents of \$196.4 million as of December 31, 2020 will be sufficient to fund its operations for at least the next 12 months.

The Company intends to seek additional capital as it prepares for the launch of Viaskin Peanut, if approved, and continues other research and development efforts. The Company may seek to finance its future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings. As a result of disruptions to the global financial markets as a result of the ongoing COVID-19 pandemic, the Company cannot guarantee that it will be able to obtain the necessary financing to meet its needs or to obtain funds at attractive terms and conditions. The ongoing COVID-19 pandemic has already caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to the Company, including reduced ability to raise additional capital when needed and on acceptable terms, if at all.

Intangible Assets

Acquired intangible assets are accounted for at acquisition cost less accumulated amortization. Acquired intangible assets are mainly composed of software amortized on a straight-line basis over their estimated useful lives comprised between one and three years. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may be impaired. The costs related to the acquisition of licenses to software are posted to assets on the basis of the costs incurred to acquire and to implement the software.

Property, Plant, and Equipment

Property, plant, and equipment are recorded at their acquisition cost.

Property, plant, and equipment are depreciated on the basis of the straight-line method over the estimated use period of the property. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the remaining lease term.

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

PROPERTY, PLANT, AND EQUIPMENT ITEM PERIOD	DEPRECIATION
Fixtures and leasehold improvements	9 years
Research and development / production tools	5 years
Research equipment and technical facilities	5 years
Computer equipment	3 years
Office equipment and furniture	5 years

Impairment of assets

The Company periodically reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset is impaired or the estimated useful life is no longer appropriate. If indicators of impairment exist and the recoverable value of the asset on an undiscounted cash flow basis is less than the carrying amount, an impairment loss is recorded to the extent the carrying amount exceeds its fair value.

Lease contracts

The Company determines whether an arrangement is a lease at contract inception by establishing if the contract conveys the right to use, or control the use of, identified property, plant, or equipment for a period of time in exchange for consideration. The Company's leases are comprised of real estate leases, leases for industrial equipment and leases for office equipment.

The Company's real estate leases typically include options and features including rent free periods, rent escalation periods, renewal options and early termination option. The lease term is defined contract-by-contract and corresponds to the non-cancelable period of the lease taking into account the optional periods that are reasonably certain to be exercised.

The Company recognizes operating lease liabilities based on the present value of the future minimum lease payments over the lease term at commencement date.

The Company does not recognize a lease liability or right of use asset for leases with a term of 12 months or less, and it does not recognize a lease liability or right of use asset for low value leases.

Operating lease right of use assets are presented as operating lease right of use assets on the consolidated balance sheet. To date, the Company has recognized a single lease cost under which the operating lease right of use and

liability are amortized on a straight-line basis over the lease term, and right of use and liability are categorized within Operating Expense in the Consolidated Statement of Operations. The operating lease cash flows are categorized under Net Cash Used in Operating Activities in the Consolidated Statement of Cash Flows. Variable costs are expensed in the period incurred.

Since the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rates based on the information available at commencement date in determining the discount rate used to calculate the present value of lease payments. As the Company has no external borrowings, the incremental borrowing rates are determined using information on indicative borrowing rates that would be available to the Company based on the value, currency and borrowing term provided by financial institutions, adjusted for company and market specific factors.

Inventories and Work in Progress

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

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

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

Financial Assets and Liabilities

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

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

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

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

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

During the years ended December 31, 2020 and December 31, 2019, the Company did not hold any derivative financial instruments.

Fair Value Measurements

Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Level 1 – Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 – Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined through the use of models or other valuation methodologies.
- Level 3 – Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement. The Company's policy is to recognize transfers between levels of the fair value hierarchy in the period the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, 2, or 3 during the periods presented.

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

Cash and Cash Equivalents

Cash includes cash on hand and demand deposits with banks. Cash equivalents include short-term, highly liquid investments, with a remaining maturity at the date of purchase of three months or less for which the risk of changes in value is considered to be insignificant. Demand deposits therefore meet the definition of cash equivalents. Cash equivalents are measured at fair value using level 1 and any changes are recognized in the Consolidated Statements of Income.

Concentration of Credit Risk

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

Share Capital

Ordinary shares are classified under Shareholders' Equity. The costs of share capital transactions that are directly attributable to the issue of new shares or options are recorded in the Financial Statements in Shareholders' Equity as a deduction from the proceeds from the issue, net of tax.

Employee benefits

Depending on the laws and practices of the countries in which the Company operates, employees may be entitled to compensation when they retire or to a pension following their retirement. For state-managed plans and other

defined contribution plans, the Company recognizes them as expenses when they become payable, with the Company's commitment being limited to our contributions.

The liability with respect to defined benefit plans is estimated using the following main assumptions:

- discount rate;
- future salary increases;
- employee turnover; and
- mortality tables.

The difference between the amount of the liability at the beginning of a fiscal year and at the close of that year is recognized through profit or loss for the portion representing the costs of services rendered and through other comprehensive income (loss) for the portion representing the actuarial gains and losses. Service costs are recognized in profit or loss and are allocated by function.

Actuarial gains and losses resulting from changes in actuarial assumptions and from differences between assumed and actual experience. Gains and losses recorded in other comprehensive income (loss) are amortized over expected remaining service periods to the extent they exceed 10% of the higher of the projected benefit obligation for the defined benefit plan.

The Company's payments for the defined-contribution plans are recognized as expenses on the statement of operations of the period with which they are associated.

Contingencies

An estimated loss from a loss contingency is recognized if the following two conditions are met:

- information available before the financial statements are issued indicates that it is probable that an asset had been impaired or a liability had been incurred at the date of the financial statements; and
- the amount of loss can be reasonably estimated.

With respect to litigations and claims that may result in a liability to be recognized, we exercise significant judgment in measuring and recognizing a liability or determining exposure to contingent liabilities that are related to pending litigation or other outstanding claims. These judgment and estimates are subject to change as new information becomes available.

Operating Income

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

Other operating income

Research Tax Credit

The Research Tax Credit (*Crédit d'Impôt Recherche*) is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria receive a tax credit that can be used against the payment of the income tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the research tax credit involve only research expenses.

The repayable portion of the Research Tax Credit in more than one year is recorded in other non-current assets.

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

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

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

The Company recognizes income under the percentage-of-completion method. The Company periodically updates its measurement of progress and updates its cumulative income recognized accordingly. The Company accrues for any excess between costs yet to be incurred and income yet to be recognized for the completion of the performance obligations. Please refer to Note 15 "Contingencies".

Research and Development Expenditures

Research and development expenditures are charged to expense as costs are incurred in performing research and development activities. Research and development costs include all direct costs, including salaries, share-based payments and benefits for research and development personnel, outside consultants, costs of clinical trials, costs related to manufacturing clinical study materials, sponsored research, clinical trials insurance, other outside costs, depreciation, and facility costs related to the development of drug candidates. The Company records upfront, non-refundable payments made to outside vendors, or other payments made in advance of services performed or goods being delivered, as prepaid expenses, which are expensed as services are performed or the goods are delivered.

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

Share-based payments

Since its incorporation, the Company has established several plans for equity compensation issued in the form of employee warrants (bons de souscription de parts de créateur d'entreprise or "BCEs"), stock options ("SO"), and restricted stock units ("RSUs") granted to employees and/or executives. The company has also established several plans for equity compensation issued in the form of "share warrants" (bons de souscription d'actions or "BSAs") granted to non-employee members of the Board of Directors and members of the Scientific Advisory Board.

These awards are measured at their fair value on the date of grant. Except for RSUs, fair value is estimated using Black and Scholes models that require inputs based on certain subjective assumptions, including the expected term of the award, and the conditions of each equity plan. The fair value is amortized in personnel expenses (allocated by function in the Consolidated Statements of Operations) on a straight-line basis over the requisite service period, and such expense is reduced for estimated forfeitures, with a corresponding increase in shareholders' equity.

The determination of the requisite service period and the estimate of RSUs awards that are expected to vest depends on the legal interpretation of the RSUs award agreements with employees under the French labor laws

and related jurisprudence. Changes in interpretations could significantly impact the accounting for the share-based payments.

At each closing date, the Company re-assesses the number of options expected to vest. If applicable, the impacts of such revised estimates are recognized in the Consolidated Statements of Operations, with a corresponding adjustment in shareholders' equity.

The awards are not subject to any market conditions.

In 2020, as the Company re-interpreted the vesting criteria for several RSUs granted in 2017, 2018 and 2019, an immaterial adjustment of the Company's personnel expenses and net loss has been made in the financial statements prepared in accordance with IFRS, as filed in the Company's Annual Report on Form 20-F for the year ended December 31, 2019, resulting in an additional expense of €5.2m (\$6.2m) and €0.5m (\$0.5m) for the years ended December 31, 2018 and 2019, respectively, with no impact on the total shareholder's equity for both periods.

These financial statements prepared in accordance with U.S. GAAP as of and for the years ended December 31, 2020 and 2019 reflect the re-interpreted vesting conditions for all periods presented.

Income Tax

Income taxes are accounted for under the asset and liability method of accounting. Deferred taxes are recognized for the future tax consequences attributable to temporary differences between the financial reporting carrying amounts and tax bases of assets and liabilities, and on tax losses, using the liability method. Differences are defined as temporary when they are expected to reverse within a foreseeable future. The Company may only recognize deferred tax assets on net operating losses if, based on the projected taxable incomes within the next three years, management determines that it is probable that future taxable profit will be available against which the unused tax losses and tax credits can be utilized. As a result, the measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. If future taxable profits are considerably different from those forecasted that support recording deferred tax assets, the Company will have to revise downwards or upwards the amount of deferred tax assets, which would have a significant impact on the Company's financial results. Tax assets and liabilities are not discounted. Amounts recognized in the Consolidated Financial Statements are calculated at the level of each tax entity included in the consolidation scope. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

Uncertain tax position

Tax benefits are recognized from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position.

Segment Information

The Company operates in a single operating segment: the conducting of research and development of epicutaneous immunotherapy products in order to market them in the future. The assets, liabilities, and operating losses recognized are primarily located in France.

Other Items in the Comprehensive Loss

Comprehensive income is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes changes in equity that are excluded from net income (loss), such as foreign currency translation adjustments. These changes in equity are presented net of tax.

Net Loss Per Share

The Company calculates basic and diluted net loss per ordinary share by dividing the net loss by the weighted-average number of ordinary shares outstanding during the period. For the years ended December 31, 2020 and 2019, the Company has excluded the effects of all potentially dilutive shares, which include outstanding ordinary stock options, warrants to purchase ordinary shares, and restricted stock units, from the weighted-average number of common shares outstanding as their inclusion in the computation for these years would be anti-dilutive due to net losses incurred.

Subsequent Events

The Consolidated Statements of Financial Position and the Consolidated Statements of operations of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that existed as of the end of the period covered. The Company has evaluated subsequent events from the balance sheet date through March 17, 2021, the date at which the consolidated financial statements are issued.

Accounting Pronouncements adopted in 2020

Effective January 1, 2020, the Company adopted ASU 2018-13 — Fair Value Measurement (Topic 820) - Disclosure Framework— Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The adoption of ASU 2018-13 did not have a material impact on the Company's financial position or results of operations.

Effective January 1, 2020, the Company adopted ASU 2018-15 - Intangibles — Goodwill and Other — Internal-Use Software (Subtopic 350-40) Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The guidance may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The adoption of ASU 2018-15 did not have a material impact on the Company's financial position or results of operations.

Effective January 1, 2020, the Company adopted ASU 2018-18 – Collaborative Arrangements — Clarifying the Interaction between Topic 808 and Topic 606, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The adoption of ASU 2018-18 did not have a material impact on the Company's financial position or results of operations.

Effective January 1, 2020, the Company adopted FASB issued ASU 2018 - 14, Compensation - Retirement Benefits - Defined Benefit Plans - General. The purpose of this update is to modify disclosure requirements for Defined Benefit Plans. It removes requirements to disclose the amounts in accumulated other comprehensive income expected to be recognized as components of net periodic benefit cost over the next fiscal year among others. It adds disclosure requirements for the items such as an explanation of the reasons for significant gains and losses related to changes in the benefit obligation for the period. The adoption of ASU 2018-14 did not have a material impact on the Company's financial position or results of operations or on our disclosures.

Accounting Pronouncements issued not yet adopted

In June 2016, the FASB issued ASU 2016-13 - Financial Instruments - Credit losses, which replaces the incurred loss impairment methodology for financial instruments in current U.S. GAAP with a methodology that reflects the Company's current estimate of expected credit losses to be incurred and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The FASB has issued ASU

2019-10 which has resulted in the postponement of the effective date of the new guidance for eligible smaller reporting companies to the fiscal year beginning after December 15, 2022 (January 1, 2023 for calendar year end companies). The guidance must be adopted using a modified-retrospective approach and a prospective transition approach is required for debt securities for which another-than-temporary impairment had been recognized before the effective date. The Company is currently evaluating the impact of the guidance on its Consolidated Financial Statements. The adoption is not expected to have a material impact on the Company's financial position or results of operations.

In January 2017, the FASB issued ASU 2017-04, Simplifying the Test for Goodwill Impairment, which modifies the goodwill impairment test and requires an entity to write down the carrying value of goodwill for the amount by which the carrying amount of a reporting unit exceeds its fair value. The FASB has issued ASU 2019-10 which has resulted in the postponement of the effective date of the new guidance for eligible smaller reporting companies to the fiscal year beginning January 1, 2023. The Company does not expect this new standard will have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)—Simplifying the Accounting for Income Taxes, which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. This guidance is effective for SEC filers eligible to the smaller reporting company status for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's Consolidated Financial Statements upon adoption.

Note 2 Significant Events and Transactions of the Periods

Clinical programs

Viaskin™ Peanut for children ages 4-11

On October 4, 2019, the Company announced that the FDA accepted for review the BLA for its investigational Viaskin™ Peanut immunotherapy for the treatment of peanut-allergic children ages 4 to 11 years.

In January 2020, the Company announced positive topline results of the three-year, open-label extension of its Phase III 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. After three years, the Company observed that 75.9% (107/141) of patients had increased their ED from baseline, and 51.8% (73/141) of patients reached an ED of at least 1,000 mg peanut protein by year three. The safety profile of Viaskin Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. During the PEOPLE trial, the most common adverse events were mild to moderate skin reactions localized to the administration site, and there was no epinephrine use deemed related to treatment. No treatment related serious adverse events were reported. One patient experienced one case of mild anaphylaxis that was determined by the investigator to be possibly related to treatment and resolved without treatment. Treatment compliance remained high throughout the study at a mean of 98% over three years of treatment. Low discontinuations due to adverse events were observed.

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, the Company 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.

On August 4, 2020, the Company announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter 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.

On January 13, 2021, the Company received written responses from the FDA to questions provided at the Type A meeting request the Company submitted in October 2020 following the CRL. The Company believe the FDA feedback provides a well-defined regulatory path forward. In exchanges with the FDA, the Company proposed potential resolutions to two main concerns identified by the FDA in the CRL: the impact of patch adhesion and the need for patch modifications. 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 1/1000 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 modified patches, FDA has requested an assessment comparing the uptake of allergen (peanut protein) between the patches in peanut allergic children ages 4-11. The FDA also recommended conducting a 6-month, well-controlled safety and adhesion trial to assess the modified Viaskin Peanut patch in the intended patient population. The Company intend to submit the protocols for the safety and adhesion study and the allergen uptake study to the FDA for review and comments in the second quarter of 2021 before initiating the trial. The Company will address details about a new human factor, or HF, validation study and additional CMC data in subsequent interactions with the FDA.

On November 2, 2020, the Company announced that our Marketing Authorization Application, or MAA, for Viaskin Peanut 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 4 to 11 years. Following the MAA validation, the EMA's Committee for Medicinal Products for Human Use, or CHMP, will review the application and provide a recommendation to the European Commission, or EC, on whether to grant a marketing authorization. We expect to receive the first set of questions from the EMA approximately 120 days post-validation, during the first quarter of 2021.

Viaskin Peanut for children ages 1-3

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

Financing

On April 8, 2019, the Company announced the closing of an underwritten global offering of an aggregate of 6,000,000 ordinary shares reserved to specified categories of investors in (i) an offering of 2,447,500 ordinary shares in the form of 4,895,000 American Depositary Shares ("ADSs") in the United States, Canada and certain other countries outside Europe, at an offering price of \$6.75 per ADS (on the basis of an exchange rate of \$1.1233 = €1.00), and (ii) a private placement of 3,552,500 ordinary shares in Europe (including France), at an offering price of €12.02 per ordinary share. Each ADS represents the right to receive one-half of one ordinary share. The gross proceeds to the Company from the global offering were approximately \$81.0 million, before deducting underwriting commissions and estimated offering expenses.

On October 15, 2019, the Company announced the closing on October 11, 2019 of an underwritten global offering of an aggregate of 9,484,066 ordinary shares reserved to specified categories of investors in (i) an

offering of 7,914,622 ordinary shares in the form of 15,829,244 American Depositary Shares (ADSs) in the United States, Canada and certain other countries outside Europe, at an offering price of \$6.59 per ADS (on the basis of an exchange rate of \$1.0945 = €1.00), and (ii) a private placement of 1,569,444 ordinary shares in Europe (including France), at a public offering price of €12.04 per ordinary share. The Company also announced the closing on October 15, 2019 of 1,368,667 additional ordinary shares in the form of 2,737,334 ADSs, at an offering price of \$6.59 per ADS, after full exercise of the underwriters' option to purchase additional ordinary shares in the form of ADSs (the "Option"). The total gross proceeds from the global offering, after exercise of the Option, were approximately \$143.0 million, before deducting commissions and estimated offering expenses.

On February 4, 2020, the Company announced the closing of an underwritten global offering of an aggregate of 7,500,000 ordinary shares in (i) a public offering of 4,535,581 ordinary shares in the form of 9,071,162 American Depositary Shares ("ADSs") in the United States, Canada and certain countries outside Europe at a public offering price of \$10.25 per ADS (on the basis of an exchange rate of \$1.0999 = €1.00), and (ii) an offering exclusively addressed to qualified investors in Europe (including France) of 2,964,419 ordinary shares at an offering price of €18.63 per ordinary share (together, the "Global Offering").

On March 2, 2020, the Company announced that the underwriters partially exercised their option to purchase 338,687 additional ordinary shares in the form of 677,374 ADSs at an offering price of \$10.25 per ADS, before deducting commissions and estimated offering expenses (the "Option"). The Option closed on March 4, 2020.

Consequently, following partial exercise of the Option, the total number of ordinary shares sold in the global offering was 7,838,687 ordinary shares, including 4,874,268 ordinary shares in the form of 9,748,536 ADSs, bringing the total gross proceeds from the global offering to approximately \$160.7 million and net proceeds of \$150.0 million.

Restructuring

The Company initiated a global restructuring plan in June 2020 to provide operational latitude to progress in the clinical development and regulatory review of investigational Viaskin™ Peanut in the United States and European Union. The company expects full implementation of the restructuring plan to result in a reduction of more than 200 jobs, resulting in a remaining global team of 90 individuals dedicated to the pursuit of innovation and scientific development of novel therapies. The Company expects full implementation of the organization-wide costs reduction measures to be completed by the second half of 2021.

The restructuring costs, accounted for \$23.6 million as of December 31, 2020, are mainly comprised of payroll expenses, restructuring-related consulting and legal fees, as well as impairment of facilities and right of use assets following resizing of facilities.

The following table summarizes restructuring effects as of December 31, 2020 included in the statement of operations:

	December 31, 2020
Employee-related expenses	19,194
Effects of restructuring on leases	2,028
Other restructuring costs	2,330
Total restructuring costs	23,552

The following table summarizes restructuring activities as of December 31, 2020 included in current contingencies and other current liabilities on the statement of consolidated financial position:

	Restructuring liabilities
Restructuring liability - January 1, 2020	—
Restructuring costs	23,552
Restructuring costs – non-cash items	(2,028)
Amounts paid	(12,137)
Restructuring liability - December 31, 2020	9,387
<i>of which current contingencies</i>	<i>1,993</i>
<i>of which other current liabilities</i>	<i>7,394</i>

COVID-19 pandemic

On March 11, 2020, the outbreak of Covid-19 was declared a pandemic by the World Health Organization. This global health crisis led many countries to impose national containment measures and travel bans. In view of this exceptional situation, the Company decided to take all measures aimed primarily at guaranteeing the safety of its employees and the continuation of ongoing clinical trials, in compliance with the directives of the authorities in each country. The Company has experienced a decrease in new patients enrolling in the ongoing clinical studies and it has had to adapt the protocols of its clinical trials because patients remain subject to travel restrictions.

The Company has assessed the impact of the uncertainties created by the pandemic. As of December 31, 2020, those uncertainties were taken into account in the assumptions underlying the estimates and judgments used by the Company. The Company will continue to update these estimates and assumptions as the situation evolves. The effects of the COVID-19 pandemic are presented in the relevant line items of the consolidated statement of financial position and the consolidated statement of operations according to the function or nature of the income or expense.

Legal Proceedings

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 alleged that the Company and its former Chief Executive Officer, its current Chief Executive Officer, and its Deputy Chief Executive 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 purchasers of our securities between February 14, 2018 and March 16, 2020.

The Company believes that the allegations contained in the amended complaint are without merit and will defend the case vigorously. The company believes this complaint will not have a material adverse effect on the Company's consolidated financial position, results of operations, or liquidity.

Note 3 Cash and Cash Equivalents

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

	December 31,	
	2020	2019
Cash	42,341	57,882
Cash equivalent	154,011	135,373
Total cash and cash equivalent as reported in statement of financial position	196,352	193,255
Bank overdrafts	—	—
Total net cash and cash equivalents as reported in the statement of cash flow	196,352	193,255

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

Note 4 Trade receivables

All the trade receivables have payment terms of less than one year. As of December 31, 2020, the accounts receivable corresponds exclusively to the amounts due under the license and collaboration agreement with Nestlé Health Science.

Note 5 Inventories and Work in Progress

Inventory consisted of the following:

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
Inventories of raw materials	128	72
Work in progress	11,591	3,539
Impairment of inventories	<u>(11,720)</u>	<u>(1,322)</u>
Total net realizable value of the inventories	<u>—</u>	<u>2,289</u>

As of December 31, 2020, in accordance with industry practice, during the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval.

Note 6 Other current assets

Other current assets consisted of the following:

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
Other tax claims	5,049	4,488
Prepaid expenses	3,162	3,596
Other receivables	<u>581</u>	<u>921</u>
Total	<u>8,792</u>	<u>9,006</u>

The other tax claims are primarily related to the VAT as well as the reimbursement of VAT that has been requested. Prepaid expenses are comprised primarily of rental and insurance expenses, as well as legal and scientific consulting fees. Prepaid expenses also include upfront payments which are recognized over the term of the ongoing clinical studies.

Note 7 Property, Plant, and Equipment

Property and equipment, net consisted of the following:

	1/1/2019	Currency translation effect	Increase	Decrease	12/31/2019
					(Amounts in thousands of U.S. Dollars)
Laboratory equipment	13,796	(259)	442	(13)	13,966
Building fixtures	5,975	(99)	654	—	6,530
Office equipment	905	(9)	12	—	908
Computer equipment	1,740	(22)	186	—	1,903
Property, plant, and equipment in progress	8,687	(147)	5,567	(1,294)	12,813
Total, gross	31,103	(536)	6,861	(1,308)	36,120
Less accumulated amortization and depreciation	(7,952)	131	(3,281)	—	(11,101)
Total, net	23,151	(405)	3,580	(1,308)	25,019

	1/1/2020	Currency translation effect	Increase	Decrease	12/31/2020
					(Amounts in thousands of U.S. Dollars)
Laboratory equipment	13,966	1,830	7,544	(268)	23,072
Building fixtures	6,530	595	697	(55)	7,767
Office equipment	908	046	16	—	970
Computer equipment	1,903	104	215	(377)	1,846
Property, plant, and equipment in progress	12,813	755	2,732	(8,473)	7,828
Total, gross	36,120	3,330	11,205	(9,173)	41,482
Less accumulated amortization and depreciation	(11,101)	(1,225)	(4,364)	—	(16,690)
Total, net	25,019	2,105	6,841	(9,173)	24,792

The depreciation and amortization expense for the years ended December 31, 2020 and 2019 was \$4.4 million and \$3.3 million, respectively.

Laboratory equipment increase in 2020 is mainly driven by commissioning of industrial equipment. For the year ended December 31, 2020, amortization includes accelerated depreciation of PP&E linked with the early termination of several leases pursuant to restructuring.

Note 8 Lease contracts

The Company initiated a global restructuring plan in June 2020 that involves a contemplated reduction in leased facilities.

The subsequent measurement of the useful life of the right-of-use assets related to each individual leases has highlighted:

- a significant decrease of the period of time over which the related asset were expected to be used by the entity; and/or
- a significant decrease in need of space for the work force.

The Company therefore recognized on impairment of the right-of-use assets related to leases. Please refer to Note 2 “Significant Events and Transactions of the Period – Restructuring”.

Future minimum lease payments under the Company's operating leases' right of use as of December 31, 2020 and 2019, are as follows:

	December 31, 2020			December 31, 2019		
	Real estate	Other assets	Total	Real estate	Other assets	Total
Current portion	4,196	88	4,284	4,503	181	4,685
Year 2	3,481	82	3,562	4,580	102	4,682
Year 3	3,182	23	3,206	4,650	76	4,727
Year 4	2,388	18	2,406	4,376	23	4,399
Year 5	771	1	773	5,863	19	5,883
Thereafter	2,011	—	2,011	5,468	—	5,468
Total minimum lease payments	16,029	212	16,241	29,441	402	29,842
Less: Effects of discounting	(2,020)	(16)	(2,037)	(4,135)	(27)	(4,161)
Present value of operating lease	14,009	196	14,205	25,306	375	25,681
Less: current portion	(3,628)	(80)	(3,708)	(3,516)	(171)	(3,686)
Long-term operating lease	10,381	116	10,496	21,791	204	21,995
Weighted average remaining lease term (years)	5.01	2.73		6.84	2.93	
Weighted average discount rate	4.62%	3.32%		4.15%	3.32%	

The Company recognizes rent expense, calculated as the remaining cost of the lease allocated over the remaining lease term on a straight-line basis. Rent expense presented in the consolidated statement of operations and comprehensive loss was:

	December 31,	
	2020	2019
Operating lease expense	4,531	4,471
Restructuring expense	2,028	—

Supplemental cash flow information related to operating leases is as follows for the period December 31, 2020 and 2019:

	December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	3,898	3,310

Note 9 Other non-current assets

Other non-current assets consisted of the following:

	December 31,	
	2020	2019
Research tax credit	22,650	10,969
Pledged securities	4,299	3,934
Deposits and other non-current financial assets	2,704	2,439
Liquidity contract	281	1,181
Total other non-current assets	29,935	18,523

Research tax credit

Due to the loss of the Small and Medium-sized Enterprises status under EU law, the Research Tax Credit is repaid three years after the tax declaration in the event the Company cannot offset it against corporate income tax due.

The repayable portion of the Research Tax Credit in more than one year is recorded in other non-current assets.

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

	Amount in thousands of U.S. Dollars
Opening balance sheet receivable as of January 1, 2019	12,399
+ Research tax credit (operating income)	10,937
- Payment received	(12,130)
- Currency translation effect	(238)
Closing balance sheet receivable as of December 31, 2019	10,969
	Amount in thousands of U.S. Dollars
Opening balance sheet receivable as of January 1, 2020	10,969
+ Research tax credit (operating income)	9,930
- Payment received	—
- Currency translation effect	1,751
Closing balance sheet receivable as of December 31, 2020	22,650

The non-current assets are also composed of portions repaid in more than one year of research tax credit, security deposits paid to premises lessors, pledged securities not used as of December 31, 2020 and the liquidity contract.

Under the liquidity contract, 112,302 treasury shares were allocated as a reduction of Shareholders' Equity as at December 31, 2020 with the cash balance being maintained in financial assets.

Note 10 Trade payables and Other Current Liabilities

10.1 Trade Payables

No discounting was performed on the trade payables to the extent that the amounts did not present payment terms longer than one year at the end of each fiscal year presented.

10.2 Other Current Liabilities

Other current liabilities consisted of the following:

	December 31,	
	2020	2019
Social debt	16,661	20,333
Deferred incomes	4,687	3,599
Tax liabilities	580	431
Other debts	999	573
Total	22,926	24,936

The other current liabilities include short-term debt to employees including employee termination allowance and benefits as part of the restructuring (Refer to Note 2, “Significant Events and Transactions of the Period – Restructuring”), bonus accruals, as well as social welfare and tax agencies.

Deferred incomes mainly include deferred incomes from the collaboration agreement with Nestlé Health Science, which amounted to \$4.7 million as of December 31, 2020.

Note 11 Financial debt and Other Non-Current Liabilities

11.1 Financial debt - Conditional Advances

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

	4th OSEO contract	BPI advance	Total
Balance sheet debt at start of period 01/01/2019	715	2,123	2,838
Repayments	(699)	(672)	(1,371)
Other including currency translation effect	(16)	7	(9)
Balance sheet debt as at 12/31/2019	—	1,458	1,458
Of which - Non-current portion			810
Of which - Current portion			648
Stated interest rate	2.05%	No	
Discount rate	1.5%-1.8%	3.2%	
Maturity (in years)	7-9	2-7	

	BPI advance
Balance sheet debt at start of period 01/01/2020	1,458
Repayments	(303)
Other including currency translation effect	112
Balance sheet debt as at 12/31/2020	1,267
Of which - Non-current portion	543
Of which - Current portion	724
Stated interest rate	No
Discount rate	3.2%
Maturity (in years)	2-7

The changes appearing in “Other transactions” are comprised of the effect of discounting conditional advances.

The portion of the conditional advances for terms longer than one year is classified as non-current liabilities, while the portion for terms of less than one year is classified as current liabilities.

Fourth OSEO Advance

In 2013, OSEO has provided assistance in the form of conditional advances as part of a collaborative research and clinical development in mite allergy in young children. Following the defection of a sponsor, the ImmunaVia project was interrupted in September 2017. The Company was required to reimburse the remaining amounts of conditional advances. The reimbursement was rescheduled in 13 monthly repayments, commencing on May 31, 2018, through May 31, 2019. This agreement with OSEO terminated in 2019.

BpiFrance Financement Interest Free Loan

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.

The initial planned repayment was scheduled in 20 quarterly repayments, starting on June 30, 2017. As of March 2, 2020, due to the COVID-19 pandemic, Bpifrance postponed the repayments for a 6-month period.

11.2 Due dates of liabilities

The following table shows the maturity of the Company's liabilities (except leases disclosed in notes 8 – "Lease contract"):

	<u>Carrying</u>	<u>2021</u>	<u>2022</u>	<u>Thereafter</u>
Short-term financial debt - Conditional advances	1,267	724	543	—
Other liabilities	23,402	22,926	475	—
Supplier accounts payable and related payables	20,338	20,338	—	—
Total liabilities	<u>45,007</u>	<u>43,989</u>	<u>1,018</u>	<u>—</u>

As detailed in Note 10.2, the current portion of other liabilities mainly includes social security and deferred incomes from the collaboration agreement with Nestlé Health Science.

Note 12 Fair value measurement

The Company reports assets and liabilities recorded at fair value on the Company's consolidated balance sheets based upon the level of judgment associated with inputs used to measure their fair value.

The fair value measurement level within the fair value hierarchy for a particular asset or liability is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial instruments not measured at fair value on the Company's consolidated statement of financial position, but which require disclosure of their fair values include cash and cash equivalents, accounts receivable, deposits, liquidity contract, accounts payable and conditional advances. The fair values of these financial instruments are deemed to approximate their carrying amount.

The fair values of cash and cash equivalents, accounts receivable, deposits, liquidity contract and accounts payable are categorized as Level 1. The fair value of conditional advance was categorized as Level 2 and was estimated based on a discounted cash flow method using the effective interest rate. For the interest-free conditional advances, the discount rate applied equal to the rate of fungible treasury bonds over the time period that corresponds to the time period of the repayment of the advances. As of December 31, 2020, the fair value of conditional advances was \$1.3million.

There has been no transfer between levels of the fair value hierarchy during the years ended December 31, 2019 and 2020.

Note 13 Share Capital Issued

The share capital, as of December 31, 2020, is set at the sum of €5,492,918,70 (\$ 6,518,498 converted at historical rates). It is divided into 54,929,187 fully authorized, subscribed and paid-up shares with a nominal value of €0.10.

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

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

The table below presents the changes in the share capital of the Company as of December 31, 2019 and 2020:

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

Date	Nature of the transactions	Share capital *	Additional paid-in capital	Number of shares
Balance as of January 1, 2019		3,770	779,465	30,157,777
04/08/2019	Capital increase by issuance of common shares	675	80,431	6,000,000
9/30/2019	Fees charged to share premium	—	(6,243)	—
10/04/2019	Capital increase by incorporation of reserve	2	(2)	18,000
10/11/2019	Capital increase by issuance of common shares	1,047	125,068	9,484,066
10/15/2019	Capital increase by issuance of common shares	151	17,991	1,368,667
12/31/2019	Fees charged to share premium	—	(10,354)	—
12/31/2019	Share-based payments	—	17,239	—
Balance as of December 31, 2019		5,645	1,003,595	47,028,510
1/16/2020	Capital increase by employee warrants	4	292	35,000
1/16/2020	Capital increase by stock options	3	140	24,990
02/04/2020	Capital increase by global offering	829	153,580	7,500,000
02/04/2020	Fees charged to share premium	—	(9,265)	—
03/04/2020	Capital increase by global offering	38	6,985	338,687
03/04/2020	Fees charged to share premium	—	(421)	—
9/30/2020	Fees charged to share premium	—	(1,735)	—
11/25/2020	Capital increase by RSU	—	—	2,000
12/31/2020	Share-based payments	—	(1,130)	—
Balance as of December 31, 2020		6,518	1,152,042	54,929,187

* Conversion in U.S. Dollars at historical rates

On April 8, 2019, the Company announced the closing of an underwritten global offering of an aggregate of 6,000,000 ordinary shares reserved to specified categories of investors in (i) an offering of 2,447,500 ordinary shares in the form of 4,895,000 American Depositary Shares (“ADSs”) in the United States, Canada and certain other countries outside Europe, at an offering price of \$6.75 per ADS (on the basis of an exchange rate of \$1.1233 =

€1.00), and (ii) a private placement of 3,552,500 ordinary shares in Europe (including France), at an offering price of €12.02 per ordinary share. Each ADS represents the right to receive one-half of one ordinary share. The gross proceeds to the Company from the global offering were approximately \$80.4 million (approximately €72.1 million), before deducting underwriting commissions and estimated offering expenses.

On October 15, 2019, the Company announced the closing on October 11, 2019 of an underwritten global offering of an aggregate of 9,484,066 ordinary shares reserved to specified categories of investors in (i) an offering of 7,914,622 ordinary shares in the form of 15,829,244 American Depositary Shares (ADSs) in the United States, Canada and certain other countries outside Europe, at an offering price of \$6.59 per ADS (on the basis of an exchange rate of \$1.0945 = €1.00), and (ii) a private placement of 1,569,444 ordinary shares in Europe (including France), at a public offering price of €12.04 per ordinary share. The Company also announced the closing on October 15, 2019 of 1,368,667 additional ordinary shares in the form of 2,737,334 ADSs, at an offering price of \$6.59 per ADS, after full exercise of the underwriters' option to purchase additional ordinary shares in the form of ADSs (the "Option"). The total gross proceeds from the global offering, after exercise of the Option, were approximately \$143.0 million (approximately €130.7 million), before deducting commissions and estimated offering expenses.

On February 4, 2020, the Company announced the closing of an underwritten global offering of an aggregate of 7,500,000 ordinary shares in (i) a public offering of 4,535,581 ordinary shares in the form of 9,071,162 American Depositary Shares ("ADSs") in the United States, Canada and certain countries outside Europe at a public offering price of \$10.25 per ADS (on the basis of an exchange rate of \$1.0999 = €1.00), and (ii) an offering exclusively addressed to qualified investors in Europe (including France) of 2,964,419 ordinary shares at an offering price of €18.63 per ordinary share (together, the "Global Offering").

On March 2, 2020, the Company announced that the underwriters partially exercised their option to purchase 338,687 additional ordinary shares in the form of 677,374 ADSs at an offering price of \$10.25 per ADS, before deducting commissions and estimated offering expenses (the "Option"). The Option closed on March 4, 2020. Consequently, following partial exercise of the Option, which partial exercise closed on March 4, 2020, the total number of ordinary shares sold in the global offering was 7,838,687 ordinary shares, including 4,874,268 ordinary shares in the form of 9,748,536 ADSs, bringing the total gross proceeds from the global offering to approximately \$160.7 million and net proceeds of \$150.0 million.

Note 14 Share-Based Payments

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

<u>Share-Based Payments instrument</u>	<u>General Meeting of Shareholders</u>	<u>Board of directors meeting</u>	<u>Grant date</u>	<u>Number granted</u>
BCE	12/16/10	6/24/11	6/24/11	24 000
BCE	12/16/10	11/22/11	11/22/11	10 039
BSA	12/16/10	6/24/11	6/24/11	8 000
BSA	12/9/11	9/25/12	9/25/12	30 000
BSA	6/4/13	7/25/13	7/25/13	73 000
SO	12/9/11	9/18/13	9/18/13	518 000
SO	6/3/14	6/3/14	6/3/14	75 000
BSA	6/3/14	3/24/15	3/24/15	10 000
SO	6/3/14	6/23/15	6/23/15	120 000
BSA	6/23/15	11/19/15	11/19/15	22 500
SO	6/3/14	9/30/15	11/19/15	195 000
BSA	6/23/15	12/15/15	2/15/16	90 000
SO	6/3/14	12/15/15	1/4/16	75 000
SO	6/3/14	4/6/16	4/21/16	33 000
SO	6/3/14	6/21/16	6/21/16	110 000
SO	6/3/14	6/21/16	8/1/16	10 000
BSA	6/21/16	6/21/16	8/21/16	20 000
SO	6/3/14	6/21/16	9/15/16	9 300

<u>Share-Based Payments instrument</u>	<u>General Meeting of Shareholders</u>	<u>Board of directors meeting</u>	<u>Grant date</u>	<u>Number granted</u>
SO	6/3/14	6/21/16	10/17/16	16 500
SO	6/3/14	6/21/16	11/15/16	8 300
BSA	6/21/16	12/9/16	2/9/17	59 000
SO	6/3/14	6/21/16	12/9/16	74 960
SO	6/3/14	6/21/16	12/15/16	1 100
SO	6/3/14	6/21/16	1/16/17	19 100
AGA	9/21/15	3/14/17	3/14/17	22 500
SO	6/3/14	6/21/16	3/15/17	7 200
SO	6/3/14	6/21/16	4/18/17	16 500
AGA	9/21/15	4/20/17	4/20/17	24 000
BSA	6/15/17	6/15/17	8/15/17	9 000
SO	6/3/14	6/15/17	6/15/17	126 000
SO	6/15/17	6/15/17	6/15/17	111 600
SO	6/15/17	6/15/17	7/17/17	30 900
SO	6/15/17	6/15/17	9/15/17	52 600
SO	6/15/17	11/17/17	12/5/17	625 200
SO	6/15/17	6/15/17	12/15/17	8 300
SO	6/15/17	6/15/17	1/15/18	15 500
SO	6/15/17	6/15/17	4/16/18	16 500
BSA	6/15/17	5/2/18	7/2/18	44 000
SO	6/15/17	6/15/17	5/15/18	16 500
SO	6/15/17	6/15/17	6/15/18	23 600
AGA	6/22/18	6/22/18	6/22/18	486 153
SO	6/22/18	6/22/18	6/22/18	50 000
SO	6/22/18	6/22/18	7/16/18	28 800
SO	6/22/18	6/22/18	8/15/18	33 500
AGA	6/22/18	9/6/18	9/6/18	450
SO	6/22/18	9/6/18	9/6/18	65 000
SO	6/22/18	6/22/18	9/17/18	80 900
SO	6/22/18	6/22/18	10/15/18	76 700
AGA	6/22/18	11/1/18	11/1/18	57 000
SO	6/22/18	6/22/18	11/15/18	26 000
SO	6/22/18	11/29/18	11/29/18	350 000
AGA	6/22/18	12/12/18	12/12/18	16 250
AGA	6/22/18	12/12/18	12/17/18	3 000
SO	6/22/18	12/12/18	12/12/18	34 000
SO	6/22/18	11/28/18	12/17/18	7 200
SO	6/22/18	11/28/18	1/15/19	9 500
SO	6/22/18	3/4/19	3/20/19	547 100
AGA	6/22/18	5/10/19	5/10/19	100 000
SO	6/22/18	11/28/18	5/15/19	7 200
SO	5/24/19	5/24/19	5/24/19	150 000
SO	5/24/19	5/24/19	6/17/19	7 200
SO	5/24/19	7/1/19	7/1/19	403 400
SO	5/24/19	7/1/19	7/22/19	75 000
AGA	5/24/19	7/31/19	7/31/19	23 750
SO	5/24/19	5/24/19	9/16/19	34 000
AGA	5/24/19	10/11/19	10/11/19	40 000
SO	5/24/19	10/11/19	10/16/19	3 500

<u>Share-Based Payments instrument</u>	<u>General Meeting of Shareholders</u>	<u>Board of directors meeting</u>	<u>Grant date</u>	<u>Number granted</u>
SO	5/24/19	10/11/19	12/16/19	53 100
AGA	5/24/19	12/19/19	12/19/19	23 600
SO	5/24/19	10/11/19	1/15/20	94 500
AGA	5/24/19	10/11/19	3/16/20	5 000
AGA	4/20/20	4/20/20	4/29/20	20 000
AGA	4/20/20	11/24/20	11/24/20	475 000
SO	4/20/20	11/24/20	11/24/20	1 216 200

In the following tables in Notes 14.1 to 14.4, exercise prices, grant date share fair values and fair value per equity instruments are provided in euros, as the Company is incorporated in France and the euro is the currency used for the grants.

14.1 Non-employee warrants

The Company's board of directors has been authorized by the shareholders' general meeting to grant BSA warrants ("Bons de Souscription d'Actions or "BSA") to non-employee's members of the Board of Directors and members of the Scientific Advisory Board. The Company no longer grants BSA warrants since 2018.

The different employee warrants plans granted by the Board of Directors are similar in their nature and conditions, except for the exercise price that is comprised between €5.13€ and €69.75.

The following table summarizes all BSA warrants activity during the year ended December 31, 2019:

	<u>Number of warrants outstanding</u>	<u>Weighted-average exercise price in Euros</u>	<u>Weighted-average remaining contractual term (in years)</u>	<u>Aggregate intrinsic value in thousands of Euros</u>
Balance as of December 31, 2018	218,008	52.78	7.36	68.7
Granted during the period	—	—	—	—
Forfeited during the period	—	—	—	—
Exercised during the period	—	—	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2019	218,008	52.78	6.36	244.6
Warrants exercisable as of December 31, 2019	218,008	52.78	6.36	244.6

The following table summarizes all BSA warrants activity during the year ended December 31, 2020:

	Number of warrants outstanding	Weighted- average exercise price in Euros	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value in thousands of Euros
Balance as of December 31, 2019	218,008	52.78	6.36	244.6
Granted during the period	—	—	—	—
Forfeited during the period	—	—	—	—
Exercised during the period	—	—	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2020	218,008	52.78	5.36	—
Warrants exercisable as of December 31, 2020	218,008	52.78	5.36	—

There were no BSA warrants granted during the years ended December 31, 2019 and 2020.

14.2 Employee warrants

The Company's Board of Directors has been authorized by the shareholders' general meeting to grant BCE warrants (Bons de Souscription de Parts de Créateur d'Entreprise or "BCE") to employees. The Company no longer grants BCE warrants since 2011.

Following the decision of the General Meeting of December 9, 2011, each BCE gives the right to subscribe to 15 shares instead of 1 share. The exercise price of each BCE has been adjusted accordingly and is therefore equal to 1/15th of the price initially set by the General Meeting.

The following table summarizes all BCE warrants activity during the year ended December 31, 2019:

	Number of warrants outstanding	Weighted- average exercise price in Euros	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value in thousands of Euros
Balance as of December 31, 2018	7,166	5.13	2.47	588.7
Granted during the period	—	—	—	—
Forfeited during the period	—	—	—	—
Exercised during the period	—	—	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2019	7,166	5.13	1.47	1,558.2
Warrants exercisable as of December 31, 2019	7,166	5.13	1.47	1,558.2

The following table summarizes all BCE warrants activity during the year ended December 31, 2020:

	Number of warrants outstanding	Weighted- average exercise price in Euros	Weighted- average remaining contractual term (in years)	Aggregate intrinsic value in thousands of Euros
Balance as of December 31, 2019	7,166	5.13	1.47	1,558.2
Granted during the period	—	—	—	—
Forfeited during the period	—	—	—	—
Exercised during the period	(1,666)	5.13	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2020	5,500	5.13	0.47	—
Warrants exercisable as of December 31, 2020	5,500	5.13	0.47	—

There were no BCE warrants grants during the years ended December 31, 2020 and 2019.

14.3 Stock options

The Company's Board of Directors has been authorized by the shareholders' general meeting to grant stock option plans ("SO") to employees.

The different stock options plans granted by the Board of Directors are similar in their nature and conditions, except for the exercise price that is comprised between €4,16 and €74,22.

All SO issued have a ten-year contractual life. SO are expensed in accordance with the following vesting conditions:

- Before June 22, 2018 and after January 15, 2020, SO granted mainly vest over four years at a rate of 25% upon the first anniversary of the issuance date and 12,5% every 6 months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions),
- Between June 22, 2018 and January 15, 2020, SO may be exercised by the beneficiary once both of the following conditions have been met:
 - Service condition: 25% upon the first anniversary of the issuance date and 12,5% every 6 months thereafter, subject to the beneficiary being still employed by the Company (except in specific contractual clause or board of directors' decisions), and,
 - Performance condition: approval of Viaskin™ Peanut by the US Food and Drug Administration,

Performance conditions which are other than market conditions, are taken into account by adjusting the number of equity instruments included in the measurement of the transaction amount but are not taken into account when estimating the fair value of the shares. Estimated achievement of performance conditions is reviewed at each reporting date.

The Company also applied a forfeiture rate for each grant according to its respective characteristics and composition. This forfeiture rate is reviewed at each reporting date.

The following table summarizes all stock options activity during the year ended December 31, 2019:

	Number of SO outstanding	Weighted-average exercise price in Euros	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value in thousands of Euros
Balance as of December 31, 2018	2,461,570	42.10	8.32	617.1
Granted during the period	1,282,800	15.49	—	—
Forfeited during the period	(742,325)	45.49	—	—
Exercised during the period	—	—	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2019	3,002,045	29.89	8.21	7,286.3
Options exercisable as of December 31, 2019	810,699	40.96	6.16	2,448.2

The following table summarizes all stock options activity during the year ended December 31, 2020:

	Number of SO outstanding	Weighted-average exercise price in Euros	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value in thousands of Euros
Balance as of December 31, 2019	3,002,045	29.89	8.21	7,286.3
Granted during the period	1,310,700	5.54	—	—
Forfeited during the period	(1,667,235)	28.49	—	—
Exercised during the period	(35,000)	7.57	—	—
Expired during the period	—	—	—	—
Balance as of December 31, 2020	2,610,510	18.75	8.17	198.8
Options exercisable as of December 31, 2020	580,023	38.79	4.94	—

Stock options have been granted during the years ended December 31, 2020 and 2019. The weighted-average exercise price of SO granted during the year ended December 31, 2020 was €5.54 per share.

As of December 31, 2020, there was €7.3 million (\$9.0 million converted at closing rate) of unrecognized SO expense that is expected to be recognized over a weighted-average period of 1.8 years.

Fair value of stock options

Determining the fair value of the share-based payments at the grant date requires judgment. The Company calculated the fair value of stock options instrument on the grant date using the Black-Scholes option pricing model. The Black-Scholes model requires the input of highly subjective assumptions, including the expected volatility, expected term, risk-free interest rate and dividend yield.

Exercise price

The exercise price of the Company's stock awards is based on the fair market value of our ordinary shares.

Risk-free interest rate

The risk-free interest rate is based on French government bonds (GFRN) with a maturity corresponding to the stock options maturity.

Expected term

The Company determines the expected term based on the average period the stock options are expected to remain outstanding.

Expected Volatility

The Company determines the expected volatility based on the historical data period corresponding to the stock options expected maturity.

Expected Dividend yield

The Company has never declared or paid any cash dividends, and it does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company uses an expected dividend yield of zero.

The Company estimated the following assumptions for the calculation of the fair value of the stock options:

Stock options per grant date	Assumptions per year ended, December 31,				
	Prior to 2017	2017	2018	2019	2020
Weighted average shares price at grant date in €	36.69	45.49	31.86	15.26	5.54
Weighted average expected volatility	45.4%	41.8%	47.1%	70.8%	87.3%
Weighted average risk-free interest rate	1.0%	(0.1)%	0.3%	(0.1)%	(0.5)%
Weighted average expected term (in years)	6.7	6.0	6.0	6.0	6.0
Dividend yield	0	0	0	0	0
Weighted average fair value of stock-options in €	17.66	17.16	13.67	9.65	3.90

14.4 Restricted stock units

The Company's board of directors has been authorized by the shareholders' general meeting to grant Restricted stock units plans ("RSU") to employees.

RSUs are measured based on the fair market value of the underlying stock on the date of grant and recognized as expense on a straight-line basis in accordance with the following vesting conditions:

- Before May 31, 2019, the vesting of RSUs granted is subject to the expiration of the presence condition of one (1) or two (2) years (except in specific board of directors' decisions). The release of RSUs for these plans is subject to the achievement of performance conditions (submission of a BLA to U.S. FDA for Viaskin™ Peanut, approval of Viaskin™ Peanut by the U.S. FDA, first sale of Viaskin™ Peanut in the United States);
- Between May 31, 2019 and November 23, 2020, the vesting of RSUs is subject either to the expiration of the presence condition of two (2) years only, or to the dual condition of expiration of the presence condition and achievement of the performance condition (date of approval of Viaskin™ Peanut by the U.S. FDA);
- Since November 24, 2020, RSUs vest over four years at a rate of 25% upon the first anniversary of the issuance date and 12.5% every 6 months thereafter, subject to the beneficiary being still employed by the Company (except in specific board of directors' decisions).

Performance conditions, are other than market conditions, which are taken into account by adjusting the number of equity instruments included in the measurement of the transaction amount but are not taken into account when estimating the fair value of the shares. Estimated achievement of performance conditions is reviewed at each reporting date.

RSU plans may be subject to a conservation period under French governing laws.

The Company applied a forfeiture rate for each grant according to its respective characteristics and composition. This forfeiture rate is reviewed at each reporting date.

The following table summarizes all RSUs activity for the year ended December 31, 2019:

	Number of RSU outstanding	Weighted average grant date fair value in Euros
Balance as of December 31, 2018	572,228	36.16
Granted during the period	187,350	15.65
Forfeited during the period	(49,433)	27.03
Released during the period	(18,000)	63.49
Expired during the period	—	—
Balance as of December 31, 2019	692,145	30.55

The service conditions have been met in 2019 for the plans granted on March 14, 2017, April 20, 2017, June 9 and 22, 2018, November 1, 2018 and December 12, 2018 with a total fair value of €19,680 thousands.

The following table summarizes all RSUs activity for the year ended December 31, 2020:

	Number of RSU outstanding	Weighted average grant date fair value in Euros
Balance as of December 31, 2019	692,145	30.55
Granted during the period	500,000	4.56
Forfeited during the period	(71,400)	7.29
Released during the period	(2,000)	68.07
Expired during the period	—	—
Balance as of December 31, 2020	1,118,745	20.35

The service conditions have been met in 2020 for the plan granted on May 10, 2019 with a total fair value of €1,288 thousands.

As of December 31, 2020, there was €2.5 million (\$3.0 million converted at closing rate) of unrecognized RSUs compensation expense that is expected to be recognized over a weighted-average period of 2.2 years.

14.5 Reconciliation of the share-based payments expenses with the consolidated statements of operations

		December 31,	
		2020	2019
Research & development	Stock-options	190	(3,158)
	RSU	(806)	(5,431)
Sales & marketing	Stock-options	2,141	381
	RSU	(24)	(651)
General & administrative	Stock-options	(119)	(3,604)
	RSU	(253)	(4,777)
Total share-based compensation (expense)		1,130	(17,239)

As of December 31, 2020, reversal of share-based payments expenses is mainly due to the restructuring plan announced on June 26, 2020 which led to significant reduction in the Company's workforce.

Note 15 Contingencies

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

	12/31/2020	12/31/2019
Current contingencies	5,016	724
Non-current contingencies	2,527	1,656
Total contingencies	7,542	2,380

The table below shows movements in contingencies:

	Pension retirement obligations	Collaboration agreement - Loss at completion	Other contingencies	Total
At January 1, 2019	1,759	—	1,454	3,213
Increases in liabilities	489	—	721	1,210
Used liabilities	—	—	(1,422)	(1,422)
Reversals of unused liabilities	—	—	—	—
Net interest related to employee benefits, and unwinding of discount	26	—	—	26
Actuarial gains and losses on defined- benefit plans	(585)	—	—	(585)
Currency translation effect	(33)	—	(30)	(63)
At December 31, 2019	1,656	—	724	2,380
<i>Of which current</i>	—	—	724	724
<i>Of which Non-current</i>	1,656	—	—	1,656
At January 1, 2020	1,656	—	724	2,380
Increases in liabilities	—	3,683	2,466	6,149
Used liabilities	—	—	(724)	(724)
Reversals of unused liabilities	(443)	—	—	(443)
Net interest related to employee benefits, and unwinding of discount	8	—	—	8
Actuarial gains and losses on defined- benefit plans	(376)	—	—	(376)
Currency translation effect	93	274	183	550
At December 31, 2020	937	3,956	2,649	7,542
<i>Of which current</i>	—	2,366	2,649	5,016
<i>Of which Non-current</i>	937	1,590	—	2,527

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

As of December 31, 2020, the Company updated its measurement of progress of the Phase 2 (“PII”) conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. The Company has recorded an accrual in the amount of the excess between the Company’s current best estimates of costs yet to be incurred and incomes yet to be recognized for the completion of the PII.

Other contingencies are mainly composed of the estimated to be incurred as part of the social costs related to restructuring, as well as estimated cost of refurbishing on lease premises (Refer to Note 2, “Significant Events and Transactions of the Period—Restructuring contingencies”).

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

	<u>12/31/2020</u>	<u>12/31/2019</u>
% social security contributions	50.0%	50.0%
Salary increases	2.0%	2.0%
Discount rate - Iboxx Corporates AA 10+	0.34%	0.77%
Expected staff turnover	10.0%	5.0%
Estimated retirement age	65	65
Life table	TGH05-TGF05	
Collective agreement	National Collective Agreement of the pharmaceutical industry ;	

Note 16 Operating income

The operating income is broken down in the following manner:

	<u>December 31,</u>	
	<u>2020</u>	<u>2019</u>
Research tax credit	9,930	10,937
Other operating income	1,346	3,771
Total	<u>11,276</u>	<u>14,708</u>

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

In 2020, the ongoing COVID-19 pandemic impacted the Company's current clinical trials, including the Phase II clinical trial conducted as part of the development activities pursuant to the collaboration and license agreement with Nestlé Health Science. The Company experienced a decrease in new patients enrolling in this Phase II clinical trial and modified the protocols of the clinical trial. As a result of these delays, the Company expects to incur additional clinical and production costs related to the Phase II clinical trial.

Accordingly, as of December 31, 2020, the Company updated its measurement of progress of the PII conducted as part of the collaboration and license agreement with Nestlé and updated the cumulative income recognized. The Company has recorded an accrual in the amount of the excess between the Company's current best estimates of costs yet to be incurred and incomes yet to be recognized for the completion of the PII.

Note 17 Allocation of Personnel Expenses

The Company had 270 average employees as of December 31, 2020, in comparison with 319 employees at December 31, 2019.

Allocation of Personnel Expenses by Function:

	December 31,	
	2020	2019
Research and Development expenses	25,703	47,571
Sales & Marketing expenses	5,217	14,231
General & Administrative expenses	9,906	28,079
Restructuring	12,066	—
Total personnel expenses	52,891	89,881

Allocation of Personnel Expenses by Nature:

	December 31,	
	2020	2019
Wages and salaries	43,330	54,027
Social security contributions	9,510	14,662
Expenses for pension commitments	2,151	2,661
Employer contribution to bonus shares	(970)	1,293
Share-based payments	(1,130)	17,239
Total	52,891	89,881

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

Note 18 Income Tax

Reconciliation between the Effective and Nominal Income Tax Expense

The following table shows the reconciliation between the effective and nominal tax expense at the nominal standard French rate 28.0% as of December 31, 2020 and 2019 (excluding additional contributions):

	December 31,	
	2020	2019
(Loss) before taxes	(159,566)	(171,401)
Theoretical company tax rate	28.00%	28.00%
Nominal tax expense	39,891	47,992
<i>Increase/decrease in tax expense arising from:</i>		
Research tax credit	2,483	3,062
Share-based compensation	543	(684)
Other permanent differences	2,460	4,504
Non recognition of deferred tax assets mainly related to tax losses	(45,368)	(54,704)
Other differences	—	(781)
Effective tax expenses - current	10	(610)
Effective tax expenses - deferred	—	—
Effective tax rate	(0.01)%	0.36%

Given the Net operating losses generated over the past years by the Company and its subsidiaries, tax from the year ended 2011 may be subject to examination by tax jurisdictions.

Deferred Tax Assets

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	290,914	216,908
Share-based compensation	7,556	7,309
Personnel-related accruals	667	1,480
Pension retirement obligations	262	464
Leases	84	69
Other	1,346	76
Total deferred tax assets	300,828	226,305
Less : Valuation allowance	(300,828)	(226,305)
Net deferred tax assets	—	—

Note 19 Commitments

Purchase Obligations

The Company has signed agreements with several contract research organizations (CRO) and part of the ongoing clinical studies for Viaskin™ Peanuts and Viaskin™ Milk products, the Company. As of December 31, 2020, we had non-cancellable contractual obligations with CRO until year ended 2023 for \$45.3 million.

Letter of credit and Collateral

The Company signed with its bank CIC an acquisition contract of monetary market fund "SICAV CM-CIC" pledged as a guarantee for the ordinary rental agreements of the leased premises in Bagneux for an amount of €400 thousand (equivalent to \$491 thousand at closing exchange rate).

A letter of credit has also been signed by the Company in April 2016 for \$143 thousand to ensure the lease of its premises of its United States subsidiary. This credit note has been extended in 2019 and 2020.

A letter of credit was also signed by the Company in May 2017 for \$300 thousand to secure the lease of its premises of its United States subsidiary. In 2015, the Company took a term deposit for a sum of €228 thousand (equivalent to \$280 thousand at closing exchange rate) over 3 years.

A Certificate of Deposit, for an initial amount of \$250 thousand was signed in order to guarantee an American Express credit cards program in the United States.

Royalty Payments

On January 7, 2009, the Company entered into an assignment, development and co-ownership agreement with Public Welfare-Hospitals of Paris (L'Assistance Publique—Hopitaux de Paris), or AP-HP, and Université Paris-Descartes, or UPD, by which the Company agreed to terms of co-ownership with AP-HP and UPD of certain U.S. and foreign patents and patent applications, referred to herein as the shared patents. The Company, and any

licensees or sublicensees the Company designates, have the exclusive right to commercial uses of the shared patents. AP-HP and UPD 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 the Company expects would include its Viaskin™ product candidates, the Company will be obligated to pay AP-HP and UPD a percentage of net sales as a royalty. This royalty varies depending on the particular patent used in the product and is in the low single digits. Additionally, if the Company licenses any of the shared patents to a third party and a licensee commercializes products covered by such shared patents, the Company will be obligated to pay AP-HP and UPD a percentage in the low single digits of the money it receives from its licensee. If the Company does not sell any of its product candidates covered by the shared patents within 30 months from the date it first markets such product candidates, AP-HP may, upon six months' notice and subject to certain exceptions, convert its exclusive right to the commercial use of the shared patents to a non-exclusive right. Any party may terminate the license in the event of another party's substantial breach which remains uncured after six months of receiving written notice of such breach. The agreement will also terminate in the event the Company ceases operations or is subject to a dissolution or bankruptcy proceedings. Absent early termination, the agreement will automatically terminate upon the expiration of the last shared patent. In the event the agreement is terminated, the Company would no longer have the exclusive right to commercial use of the shared patents, though it would retain its shared ownership rights. In addition, its ownership stake in certain jointly made improvements covered by the shared patents would survive termination of the agreement. The longest lived patent rights licensed to the Company under the agreement are currently expected to expire in 2033. To date, this agreement has not had an impact on the Company's financial statements.

Note 20 Relationships with Related Parties

The compensation amounts for 2020 presented below, which were awarded to the Directors and Officers of the Company totaled \$8.3 million. The recipients of this compensation are "related parties" under applicable French law and may not be considered executive officers or related parties under comparable SEC and Nasdaq rules and regulations applicable to the Company.

	December 31,	
	2020	2019
Short-term benefits	5,226	7,888
Post-employment benefits	34	64
Termination benefits	829	4,904
Share-based payment	<u>2,209</u>	<u>4,168</u>
Total	8,297	17,024

The methods for the valuation of the benefit related to share-based payments are presented in Note 14-Share-Based Payments.

A schedule of amounts payable to related parties:

	December 31,	
	2020	2019
Compensation	2,049	3,969
Pension obligations	<u>122</u>	<u>79</u>
Total	2,172	4,048

As of December 31, 2020, the amount of compensation included severance pay for Executive Committee members in connection with restructuring announcement in June 2020.

Note 21 Loss Per Share

The basic loss per share is calculated by dividing the net loss attributable to the shareholders of the Company by the weighted average number of ordinary shares outstanding during the course of the fiscal year. As the Company was in a loss position for the years ended December 31, 2020 and 2019, the diluted loss per share is equal to basic loss per share because of the effects of potentially dilutive shares were anti-dilutive given the Company's net loss.

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

	December 31,	
	2020	2019
Net loss	(159,555)	(172,011)
Weighted average number of ordinary shares	54,092,469	37,007,247
Net loss per share attributable to ordinary shareholders, basic and diluted (\$/share)	(2.95)	(4.65)

The following is a summary of the ordinary share equivalents which were excluded from the calculation of diluted net loss per share for the periods indicated in number of potential shares:

	December 31,	
	2020	2019
Non-employee warrants	225,008	225,008
Employee warrants	82,500	107,490
Stock options	2,610,510	3,002,045
Restricted stock units	1,118,245	692,145

Note 22 Events after the Close of the Fiscal YearClinical programs

On January 14, 2021, the Company announced the receipt of written responses from the FDA to questions provided in the Type A meeting request the Company submitted in October 2020. The FDA agreed with the Company's 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 1/1000 one peanut) remains unchanged and performs in the same way it has performed previously. The FDA recommended conducting a 6-month, well-controlled safety and adhesion trial to assess the modified Viaskin™ Peanut patch in the intended patient population. The Company has announced that it plans to initiate the selection of modified prototype patches in the first quarter of 2021.

BY-LAWS

(updated by decision of the CEO on November 25, 2020)

DBV Technologies
Limited Company with share capital of €5,492,918.70
177-181 avenue Pierre Brossolette - 92120 Montrouge, France
Nanterre Trade and Companies Register No. 441 772 522

I. - CHARACTERISTIC FEATURES OF THE COMPANY

Article 1 - Form

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

Article 2 - Name

The name of the Company is: "DBV Technologies"

Article 3 - Registered office

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

Article 4 - Corporate Purpose

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

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

Article 5 - Term

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

Article 6 - Share capital

The share capital has been set at €5,492,918.70.

It is divided into 54,929,187 ordinary shares with a par value of 10 euro cents (€0.10) each. All of the shares have been fully subscribed, and their full amount paid up in cash.

Article 7 - Changes to the share capital

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 8 - Financial year

The financial year runs from January 1 to December 31.

II. - ADMINISTRATION OF THE COMPANY

Article 9 - Executive Management exercise method

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

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

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

A. The Board of Directors

Article 10 - Composition of the Board of Directors

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

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

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

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

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

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

Article 11 - Board Discussions

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

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

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

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

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

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

Article 12 - The Board's powers

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

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

Article 13 - The Chairman of the Board of Directors

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

No one aged 70 or over may be appointed as Chairman. If the incumbent Chairman reaches this age during a financial year, their duties will automatically end following the Ordinary General Meeting of Shareholders convened to approve the financial statements for that financial year.

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

Article 14 - Non-Voting Board Members

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

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

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

B. The Executive Management

Article 15 - Chief Executive Officers and Deputy Chief Executive Officers

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

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

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

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

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

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

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

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

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

III - GENERAL MEETING OF SHAREHOLDERS

Article 17 - General Meeting of Shareholders

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

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

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

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

Article 18 - Invitations

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

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

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

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

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

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

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

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

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

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

Article 19 - Agenda

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

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

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

Article 20 - Shareholders' attendance at the Meetings

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

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

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

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

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

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

Article 21 - Shareholder representation

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

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

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

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

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

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

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

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

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

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

Article 22 - Attendance sheet

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

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

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

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

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

Article 23 - Quorum

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

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

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

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

Article 24 - Minutes

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

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

Article 25 - Disclosure of documents

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

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

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

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

Article 26 - Ordinary General Meeting of Shareholders

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

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

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

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

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

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

Article 27 - Extraordinary General Meeting of Shareholders

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

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

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

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

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

Article 28 - Special Meeting

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

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

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

IV. - THE COMPANY'S SECURITIES

Article 29 - Payment for the shares

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

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

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

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

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

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

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

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

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

Article 31 - Transfer of the shares

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

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

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

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

Article 32 - Crossing of thresholds

Any private individual or legal entity referred to in Articles L. 233-7, L. 233-9, and L. 223-10 of the French Commercial Code who comes to directly or indirectly hold a number of shares representing a percentage of the Company's share capital or voting rights higher than or equal to 2.5% or a multiple of that percentage, either on a stand-alone basis or in concert, must inform the Company of the total number of shares, voting rights, and securities granting access to the share capital or to voting rights immediately or in the future that they hold, via registered letter with a request for an acknowledgment of receipt sent to the registered office within a period of four trading days, prior to the market close as from the point when they crossed said percentage threshold(s).

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

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

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

Article 33 - Rights and obligations attached to the shares

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

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

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

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

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

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

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

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

Article 34 - Beneficial & Bare ownership

The shares are indivisible as regards the Company.

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

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

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

V. - COMPANY FINANCIAL STATEMENTS

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

- a) The Board of Directors will draw up an inventory and the annual financial statements at the end of each financial year, and will then prepare the management report. Where applicable, the Board of Directors will prepare and publish the consolidated financial statements, together with the report regarding the management of the Group.
- b) The Ordinary General Meeting of Shareholders will approve the annual company financial statements within a period of six months following the financial year-end, after familiarizing itself with the management report and the report prepared by the Statutory Auditors; the consolidated financial statements and the report regarding the management of the Group will be presented at that Meeting, if required.

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

Article 36 - Audit of the financial statements

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

Article 37 - Allocation of the amounts available for distribution

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

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

Write-down differences are not available for distribution.

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

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

VI - LIQUIDATION OF THE COMPANY

Article 38 - Liquidation

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

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

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

VII - MISCELLANEOUS ITEMS

Article 39 - Powers

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



**DBV TECHNOLOGIES
PLAN RULES OF THE
2020 STOCK OPTION PLAN (US VERSION)**

Purpose and background of the Plan:

DBV Technologies (“**DBV Technologies**” or the “**Company**”) is granting to its employees options to purchase and/or subscribe shares of DBV Technologies under this 2020 Stock Option Plan (the “**Plan**”). Through this Plan, employees can become shareholders of DBV Technologies, rewarding their contributions to its development.

The implementation of this Plan is based on the authorization given by the shareholders of the Company at the Annual General Meeting of Shareholders of DBV Technologies held on April 20, 2020, in its 32nd resolution, which authorized the Board of Directors to award options to purchase and/or subscribe shares of DBV Technologies (such awards being referred to as “**Options**”) to employees of the Company and its subsidiaries.

The grant of Options under this Plan was made on November 24, 2020 (the “**Grant Date**”), by the Board of Directors of the Company. Each Option entitles its holder to acquire/subscribe to one share of the Company at a preferred exercise price, subject to the satisfaction of a continued employment condition and to the other terms and conditions set forth in this Plan.

This document sets forth the terms of the Plan for participants who are employed by a U.S. company of the DBV Technologies Group on the Grant Date.

1 Participants and number of Options granted to each

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

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

The Exercise Price is € 4.16, which is equal to the price of the Shares on Euronext Paris on the Grant Date, but is not be less than the average of the share prices quoted over the twenty (20) trading days preceding the Grant Date.

Each Participant will be informed of the grant by a notification letter (which may be sent electronically on the website of the plan administrator mandated by the Company (the "Plan Administrator")). The Participant must acknowledge receipt of the notification and accept the grant within 30 days of the date of the notification letter, failing which the Company may cancel the grant, without prior notice or compensation. The acceptance procedure will be set forth in the notification letter. Acceptance of the grant by the Participant will also include an acceptance of its terms and of these Plan rules, including Annex 1.

2. Vesting schedule and dates

The Options will vest in installments over a four-year period starting from the Grant Date, according to the schedule set forth below and subject to the satisfaction of the continued employment condition and to the other terms and conditions set forth in this Plan.

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

- 25 % of the Options shall be eligible to vest on November 24, 2021, 12 months following the Grant Date.
- an additional 12.5 % of the Options shall be eligible to vest on May 24, 2022, 18 months following the Grant Date.
- an additional 12.5 % of the Options shall be eligible to vest on November 24, 2022, 24 months following the Grant Date.
- an additional 12.5 % of the Options shall be eligible to vest on May 24, 2023, 30 months following the Grant Date.
- an additional 12.5 % of the Options shall be eligible to vest on November 24, 2023, 36 months following the Grant Date.
- an additional 12.5 % of the Options shall be eligible to vest on May 24, 2024, 42 months following the Grant Date; and
- an additional 12.5 % of the Options shall be eligible to vest on November 24, 2024, 48 months following the Grant Date.

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

“Cause” as a reason for a Participant’s termination of employment shall have the meaning assigned such term in the employment, severance or similar agreement, if any, between such Participant and his or her employer, provided, however that if there is no such employment, severance or similar agreement in which such term is defined, then “Cause” shall mean any of the following acts by the Participant, as determined by the Company: gross neglect of duty, prolonged absence from duty without the consent of the Company or applicable Group Company, material breach by the Participant of any published Company or applicable Group Company code of conduct or code of ethics; intentionally engaging in activity that is in conflict with or adverse to the business or other interests of the Company or applicable Group Company; or willful misconduct, misfeasance or malfeasance of duty which is reasonably determined to be detrimental to the Company or applicable Group Company. The determination of the Company as to the existence of “Cause” shall be conclusive on the Participant.

3. Manner of Exercise

Once vested, the Options can be exercised, on one or more occasions at the Participants’ discretion, at any time between the first anniversary date of the Grant Date (included), and the tenth anniversary date of the Grant Date, on November 24, 2030 (included) at midnight Paris Time (the “Exercise Period”), subject to the terms and conditions of this Plan. Thereafter, the Options will automatically lapse.

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

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

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

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

4. Continued Employment Condition

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

If employment or corporate office is terminated or lapses at any time, then any Option that was previously exercisable on or prior to the termination date (the “**Termination Date**” as defined below) according to the vesting schedule set forth in Article 2, shall then be exercisable during a 90 day-period starting from the Termination Date. After this period the vested Options shall be immediately cancelled without prior notice or compensation. Any Option that has not vested on or prior to the Termination Date shall also be immediately cancelled without prior notice or compensation.

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

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

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

5. Exceptions to the Continued Employment condition

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

a) Death of the Participant

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

b) Disability of the Participant

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

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

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

c) Retirement of the Participant

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

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

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

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

6. Transfer of shares

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

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

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

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

7. Characteristics of the Shares

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

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

8. Adjustment

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

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

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

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

9. Restructuring and mergers

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

10. Social and tax treatment

The Participant is responsible for making declarations and payments to be made or owed by him/her under applicable law and particularly in respect of his/her tax liabilities.

Applicable social security law and tax law vary depending on the country of residence of the Participants.

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

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

11. Limitation of rights

The Options are not transferrable.

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

The Options are separate from the Participant's employment contract and are not part of it. They are not taken into account to compute termination payments, pensions or any other payments made in the context of employment relationship termination.

None of the provisions which are set out in the Plan constitute an element of the employment contract of a Participant. The rights and obligations deriving from the employment relationship between the Participant and DBV Technologies or a Group Company shall in no way be affected by the Plan from which they are completely distinct. Participation in the Plan shall not confer any right relating to the continuation or creation of any employment relationship or any right upon termination of any such relationship.

12. Construction of the Plan and governing law

It will be the responsibility of the Board of Directors to construe the provisions of the Plan, if required, which may delegate this power to the Chief Executive Officer or to the Global Head of Human Resources of the Group.

This Plan is governed and shall be construed in accordance with French law, and any claim relating thereto will be subject to the jurisdiction of the courts within the jurisdiction of the Court of Appeal of Paris. For Participants who are who are employed by a U.S. Company of the DBV Technologies Group, this Plan shall be construed in accordance with Section 409A of the United States Internal Revenue Code.

13. Modification of the plan

The terms of this Plan may be amended or supplemented by the Board of Directors (i) if it deems such amendment or supplement to be appropriate and not materially adverse to the interest of the affected Participants or (ii) by mutual agreement with the affected Participants.

More generally, in the event of a change in any legal, regulatory or accounting requirements applicable to the Plan, or any change in the interpretation thereof, in particular with respect to the fiscal or social treatment of any grant or exercise of Options, or delivery of Shares under the Plan, affecting the Company, any Group Company or any Participants, the terms of the Plan may be amended or supplemented by the Board of Directors, in its discretion and in the manner that it deems appropriate, in response to such change. For example, the Board of Directors may choose to shorten or lengthen the Vesting Period, the Exercise Period and/or to introduce a mandatory lock-up period and/or waive or modify any condition to Exercise Conditions and/or introduce new conditions. Furthermore, the Board of Directors may, if it deems the delivery of Shares to any Participant following exercise of Options would be impossible or inopportune, choose to pay instead an amount in cash of equivalent value, net of taxes and social charges. The amount and timing of any such payment would be determined by the Board of Directors in its discretion, by reference to the number and timing of any Shares to be otherwise delivered to Participants hereunder following the exercise of Options, to be valued by the Board of Directors on or around the scheduled delivery date, or by reference to an average price over a period preceding such date.

Participants shall not be entitled to any indemnification for any loss of value and/or increased tax or social costs resulting from any such amendments or supplements to the Plan, irrespective of whether such loss or increase is of general application or is specific to them in view of their personal situation.

* * *

Annex 1

Information Notice on the Protection of Personal Data

By participating in the Plan, the Participant acknowledges that his/her personal information be subject to electronic data processing carried out under the control of the Company, with the assistance of his/her employer, in accordance with French Law n°78-17 of January 6, 1978 on data processing, data files and individual liberties, the EU Regulation on Data protection (2016/679) of April 27, 2016 (GDPR) and applicable local laws. It shall be implemented on the basis of legitimate interest (Article 6(1)(f) of the GDPR) because it is necessary for the administration of his/her rights under the plan and on for compliance of legal obligations (Article 6(1)(c) of the GDPR), for all purposes relating to the implementation of the Plan, *i.e.*:

- (i) administering and maintaining Participant records.
- (ii) providing information to members of the Group, registrars, brokers or third-party administrators of the Plan.
- (iii) providing information to future purchasers of the Company or of the business in which the Participant works.
- (iv) transferring information about the Participant to France or to another country or territory outside of his/her home country and/or of the European Economic Area that may not provide the same statutory protection for the information as the Participant's home country; and
- (v) complying with legal obligations.

All personal information subject to the electronic data processing is mandatory for the participation to the Plan. All this information will be transmitted (and be transferred to France) to and used for account administration and electronic storage of this data, by the internal departments of the Group in charge of the management of his/her shareholder's account, and to external entities designated to manage the same, and to all persons statutorily or expressly authorized by DBV Technologies or by an employer to hold and process this information (in particular the holder of shareholders accounts), as well as to any future acquirer of DBV Technologies or his/her employing company or the business in which he/she is working within the duration of the Plan. This personal information shall be retained for the time required for the completion of the Plan and for the purposes of the management of the shareholder's account, until he/she sells all his/her DBV Technologies shares under the Plan, and thereafter for archiving purposes.

Every Participant will be able to exercise a right to access, to modify and to rectify, and as well as to delete (once he/she no longer holds any Shares under the Plan) any information relating to him/her. Furthermore, each Participant will have the right to restriction of processing and to object to processing as well as the right to data portability. The right of data portability shall allow the Participant to recover his/her data directly or to transfer them or have them transferred to another data controller (subject to legal limits). He/she will have a right to define the directives in relation to the registration, the removal and the communication of his/her personal data after his/her death.

In some countries, local regulations require the express consent of the Participant for the processing and transfer of his/her personal data. In such a case, the Participant's consents, under the acceptance procedure, to the collection, use, storage and transfer of his/her personal data, within the framework of local law. Furthermore, local law may provide that he/she has the right to withdraw his/her consent for the processing of his/her personal data. However, his/her personal data is necessary for the processing of his/her participation to the Plan, the holding of his/her Shares under the Plan and the execution of all operations related to his/her investment. Accordingly, he/she will be able to exercise his/her right to withdraw his/her consent only when all the Shares held under the Plan have been sold.

The Company has appointed a data protection officer, who is responsible for compliance with this notice and can be contacted at the following address: dataprivacy@dbv-technologies.com

The Participant have the right to lodge a complaint with his/her supervisory authority (in France, the supervisory authority is the CNIL), concerning the protection of personal data.



DBV TECHNOLOGIES
PLAN RULES FOR THE
2020 FREE SHARE PLAN (US VERSION)

Purpose and background of the Plan:

DBV Technologies (“**DBV Technologies**” or the “**Company**”) is granting to its employees a right to receive shares of DBV Technologies for free under this 2020 Free Share Plan (the “**Plan**”). Through this Plan, employees can become shareholders of DBV Technologies, rewarding their contributions to its development.

The implementation of this Plan is based on the authorization given by the shareholders of the Company at the Annual General Meeting of Shareholders of DBV Technologies held on April 20, 2020, in its 31st resolution, which authorized the Board of Directors to award free shares (such awards being referred to as “**Restricted Stock Units**”) to employees of the Company and its subsidiaries.

The grant of Restricted Stock Units under this Plan was made on November 24, 2020 (the “**Grant Date**”), by the Board of Directors of the Company. Each Restricted Stock Unit entitles its holder to receive one share of the Company, subject to the satisfaction of a continued employment condition and to the other terms and conditions set forth in this Plan.

This document sets forth the terms of the Plan for participants who are employed by a U.S. company of the DBV Technologies Group on the Grant Date.

1 Participants and number of shares granted to each

Individuals receiving restricted stock units under this Plan (“**Participants**”) are employees and corporate officers of the Company and those companies in which it holds directly or indirectly a majority of the share capital and/or voting rights (“**Group Companies**”). The list of Participants and the number of Restricted Stock Units granted to each has been fixed by the Board of Directors on the Grant Date.

Each Participant will be informed of the grant by a notification letter (which may be sent electronically on the website of the plan administrator mandated by the Company (the “**Administrator**”). The Participant must acknowledge receipt of the notification and accept the grant within 30 days of the date of the notification letter, failing which the Company may cancel the grant, without prior notice or compensation. The acceptance procedure will be set forth in the notification letter. Acceptance of the grant by the Participant will also include an acceptance of its terms and of these Plan rules, including Annex 1.

2 Vesting schedule and dates

The right to receive Shares under the Restricted Stock Units will vest in installments over a four-year period starting from the Grant Date, according to the schedule set forth below and subject to the satisfaction of the continued employment condition and to the other terms and conditions set forth in this Plan.

For each Restricted Stock Unit, the period between the Grant Date and its scheduled “**Vesting Date**” set forth below is referred to as its “**Vesting Period**”.

<u>Vesting</u>	<u>Delivery</u>
25 % of the restricted stock units shall be eligible to vest on November 24, 2021, 12 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following November 24, 2022.
An additional 12.5 % of the restricted stock units shall be eligible to vest on May 24, 2022, 18 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following November 24, 2022.
an additional 12.5 % of the restricted stock units shall be eligible to vest on November 24, 2022, 24 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following the Vesting Date.
an additional 12.5 % of the restricted stock units shall be eligible to vest on May 24, 2023, 30 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following the Vesting Date.
an additional 12.5 % of the restricted stock units shall be eligible to vest on November 24, 2023, 36 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following the Vesting Date.
an additional 12.5 % of the restricted stock units shall be eligible to vest on May 24, 2024, 42 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following the Vesting Date.
an additional 12.5 % of the restricted stock units shall be eligible to vest on November 24, 2024, 48 months following the Grant Date.	The Shares underlying these Restricted Stock Units will be delivered on the first business day following the Vesting Date.

In the event that the Participant’s employment or corporate office is involuntary terminated other than for cause within twelve months following the date of the consummation of a change of control of the Company as defined in Article L. 233-3 of the French Commercial Code, the vesting of each of the Participant’s Restricted Stock Units (including the Restricted Stock Units that have not vested) shall be automatically accelerated in full and the underlying Shares shall be delivered as soon as practicable thereafter. In the event of change in control occurring prior to the second anniversary of the Grant Date, such delivery shall be made on the first business day following such second anniversary.

“Cause” as a reason for a Participant’s termination of employment shall have the meaning assigned such term in the employment, severance or similar agreement, if any, between such Participant and his or her employer, provided, however that if there is no such employment, severance or similar agreement in which such term is defined, then “Cause” shall mean any of the following acts by the Participant, as determined by the Company: gross neglect of duty, prolonged absence from duty without the consent of the Company or applicable Group Company, material breach by the Participant of any published Company or applicable Group Company code of conduct or code of ethics; intentionally engaging in activity that is in conflict with or adverse to the business or other interests of the Company or applicable Group Company; or willful misconduct, misfeasance or malfeasance of duty which is reasonably determined to be detrimental to the Company or applicable Group Company. The determination of the Company as to the existence of “Cause” shall be conclusive on the Participant.

3 Continued employment condition

The vesting of each Participant’s Restricted Stock Units on their respective Vesting Date is subject to him or her remaining an employee or executive corporate officer of the Company or another Group Company for the full duration of the applicable Vesting Period, up to and including the Vesting Date. Such employment must be continuous and without interruption. Exceptions to this condition are set forth below.

If employment or corporate office is terminated or lapses at any time during the Vesting Period, then all Restricted Stock Units eligible to vest according to the vesting schedule set forth in Article 2 on or after the Termination Date (as defined below) shall be immediately cancelled, without prior notice or compensation.

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

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

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

4 Exceptions to the Continued Employment Condition

Notwithstanding the provisions of Article 3, an exception to the Continued Employment Condition shall be made in the following cases:

a) Death of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, the Shares underlying the outstanding Restricted Stock Units shall be delivered within 90 days of the date of death to the Participant's heirs or assignees, or in escrow if they cannot be identified.

For Participants who are employed by the Company or a French company of the DBV Technologies Group or by any other entity of the DBV Technologies Group which is not a U.S. company, the heirs or assignees may request an early delivery of the Shares underlying the outstanding Restricted Stock Units within six (6) months from the date of death of the Participant.

The Shares received will be freely transferable.

b) Disability of the Participant

For Participants who are employed by a U.S. company of the DBV Technologies Group, "disability" shall have the meaning provided for under Section 409A of the Internal Revenue Code. Following a disability, the Shares underlying the outstanding Restricted Stock Units shall be delivered within 90 days of notification to the Company.

For Participants who are employed by the Company or a French company of the DBV Technologies Group or by any other entity of the DBV Technologies Group which is not a U.S. company, "disability" shall have the meaning provided in the second or third of the categories provided for by Article L. 341-4 of the French Social Security Code. Following a disability, the affected may request early delivery of the Shares underlying the outstanding Restricted Stock Units.

The Shares received will be freely transferable.

c) Retirement of the Participant

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

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

Following a retirement, the Participant shall remain eligible to receive Shares in respect of Restricted Stock Units scheduled to vest on the first scheduled Vesting Date occurring after the effective date of retirement. Restricted Stock Units with a subsequent Vesting Date shall be immediately cancelled, without prior notice or compensation.

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

5 Delivery and Custody of the Shares

On the first Paris business day following each scheduled Vesting Date, the Company will deliver to each Participant the Share underlying the Restricted Stock Units that will have vested on such Vesting Date, following compliance with the conditions and criteria of Vesting set forth in this Plan.

The Company will in its sole discretion decide on the custodial arrangement of the Shares, in accordance with applicable laws and practices.

As an exception to the foregoing, the Shares underlying the Restricted Stock Units that will have vested prior to the second anniversary of the Grant Date, will be delivered on the first [Paris] business day following the second anniversary and not before, except in case of death or disability.

Shares delivered on or after the second anniversary of the Grant Date will be freely transferable and not subject to any lock-up period.

In all cases, Shares received under this Plan may not, pursuant to the current provisions of Article L. 22-10-59 of the French Commercial Code, be transferred or sold:

- During the period of thirty calendar days that precede the date on which the annual, half-year or quarterly results of the Company are published. and
- By the members of the Board of directors, the Chief Executive Officer or Deputy Executive Officers, if any, and by any employee aware of insider information, within the meaning of Article 7 of regulation (EU) n ° 596/2014 of the European Parliament and of the Council of 16 April 2014 on Market Abuse, which has not been made public.

Should periods defined under Article L. 22-10-59 of the French Commercial Code change over time, or be deleted, any new provision will automatically replace the provisions described above.

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

6 Characteristics of the Shares

The Shares delivered to the Participants will be new or existing ordinary shares, at the choice of the Board of Directors. In the absence of a choice before the delivery date, then the Shares will be new shares.

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

7 Adjustment of the number of Shares

During the Vesting Period, in the event of a redemption or reduction of share capital, a change in the allocation of profits, a grant of free shares to all of the shareholders, an increase in share capital by incorporation of reserves, profits or share premium, a distribution of reserves, a share buy-back at a price above the share price on the stock exchange or any issue of equity instruments that includes subscription rights reserved for the shareholders, the maximum number of Shares awarded pursuant to the Plan may be adjusted by the Board of Directors of the Company in order to take into account such transaction, in a similar manner to the adjustment modalities provided by French law governing options to subscribe or acquire shares. The same applies in case of stock-split or reverse stock-split with respect to the Shares.

If such a situation is not covered by existing French law governing options to subscribe or acquire shares, the General Meeting of shareholders or the Board of Directors when deciding to proceed with such securities issuance or other modification of the share capital may adopt any adjustment measures necessary to protect the rights of the Participants, using by analogy French law governing similar cases.

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

In accordance with the 31st resolution of the Combined General Meeting dated April 20, 2020, the Restricted Stock Units which would have been freely awarded pursuant to such an adjustment will be deemed to have been awarded on the same day as the Restricted Stock Units initially awarded on the Grant Date.

8 Restructuring and mergers

In accordance with Article L. 225-197-1 III of the French Commercial Code, in case of a cashless share exchange (*échange sans soulte*) as a result of a merger or a split (*scission*) achieved in accordance with applicable law during the Vesting Period, all the conditions provided in this Plan at the exchange date and, in particular, any Vesting conditions and remaining Vesting Period, will remain applicable to the Restricted Stock Units and to the Shares received in exchange.

9 Tax and social treatment

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

Each Participant is responsible for inquiring about the social and tax treatment applicable to him/her in any jurisdiction due to the award of Restricted Stock Units, the Vesting or the delivery of Shares, or at the time of the transfer of the Shares or upon payment of any dividend.

In the event that, as a consequence of the award of Restricted Stock Units, the Vesting or the delivery of Shares, DBV Technologies or a Group Company would have to pay taxes, social security contributions or any other taxes or governmental contribution on behalf of a Participant, DBV Technologies reserves the right to defer or prevent the delivery of the Shares until such time as the Participant has paid the corresponding amount to DBV Technologies or the relevant Group Company. DBV Technologies or, if applicable, the relevant Group Company has the right (i) to deduct the amount of these taxes, social security contributions, taxes or governmental contribution from the salary or other amount owed to the Participant, or (ii) to transfer or sell all or part of the Shares in order to fulfil the Participant's obligations, the proceeds being directly paid to DBV Technologies or the relevant Group Company.

Participants who have been employed in France during the Vesting Period but who would no longer be tax residents of France at the time of the transfer of the Shares will be subject to a withholding tax in France upon sale of the Shares. The tax will be deducted by the bank administering the Plan and may be withheld from the proceeds of such sale. The balance of the proceeds of the sale will only be credited to the personal account of the Participant after payment of any such tax due.

10 Limitation of rights

The Restricted Stock Units are not transferrable.

During the Vesting Period, the Participants are not the owners of the Shares which are not vested and do not have any right attached to such Shares, including voting rights or rights to dividends. They shall become full owners of the Shares and attached rights only upon delivery.

The Restricted Stock Units are separate from the Participant's employment contract and are not part of it. They are not taken into account to compute termination payments, pensions or any other payments made in the context of employment relationship termination.

None of the provisions which are set out in the Plan constitute an element of the employment contract of a Participant. The rights and obligations deriving from the employment relationship between the Participant and DBV Technologies or a Group Company shall in no way be affected by the Plan from which they are completely distinct. Participation in the Plan shall not confer any right relating to the continuation or creation of any employment relationship or any right upon termination of any such relationship.

11 Interpretation of the Plan and Governing Law

It will be the responsibility of the Board of Directors to construe the provisions of the Plan, if required, which may delegate this power to the Chief Executive Officer or to the Global Head of Human Resources of the Group.

This Plan is governed and shall be construed in accordance with French law and any claim relating thereto will be subject to the jurisdiction of the courts within the jurisdiction of the Court of Appeal of Paris. For Participants who are who are employed by a U.S. Company of the DBV Technologies Group, this Plan shall be construed in accordance with Section 409A of the United States Internal Revenue Code.

12 Amendment of the Plan

The terms of this Plan may be amended or supplemented by the Board of Directors (i) if it deems such amendment or supplement to be appropriate and not materially adverse to the interest of the affected Participants or (ii) by mutual agreement with the affected Participants.

More generally, in the event of a change in any legal, regulatory or accounting requirements applicable to the Plan, or any change in the interpretation thereof, in particular with respect to the fiscal or social treatment of any rights, payments or shares granted under the Plan, affecting the Company, any Group Company or any Participants, the terms of the Plan may be amended or supplemented by the Board of Directors, in its discretion and in the manner that it deems appropriate, in response to such change. For example, the Board of Directors may choose to shorten or lengthen the Vesting Period and/or to introduce a mandatory lock-up period and/or waive or modify any condition to Vesting and/or introduce new conditions. Furthermore, the Board of Directors may, if it deems the delivery of shares to any Participant would be impossible or inopportune, choose to pay instead an amount in cash of equivalent value, net of taxes and social charges. The amount and timing of any such payment would be determined by the Board of Directors in its discretion, by reference to the number and timing of any Shares to be otherwise delivered hereunder, to be valued by the Board of Directors on or around the scheduled delivery date, or by reference to an average price over a period preceding such date.

Participants shall not be entitled to any indemnification for any loss of value and/or increased tax or social costs resulting from any such amendments or supplements to the Plan, irrespective of whether such loss or increase is of general application or is specific to them in view of their personal situation.

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- (i) administering and maintaining Participant records;
- (ii) providing information to members of the Group, registrars, brokers or third-party administrators of the Plan;
- (iii) providing information to future purchasers of the Company or of the business in which the Participant works;
- (iv) transferring information about the Participant to France or to another country or territory outside of his/her home country and/or of the European Economic Area that may not provide the same statutory protection for the information as the Participant's home country; and
- (v) complying with legal obligations.

All personal information subject to the electronic data processing is mandatory for the participation to the Plan. All this information will be transmitted (and be transferred to France) to and used for account administration and electronic storage of this data, by the internal departments of the Group in charge of the management of his/her shareholder's account, and to external entities designated to manage the same, and to all persons statutorily or expressly authorized by DBV Technologies or by an employer to hold and process this information (in particular the holder of shareholders accounts), as well as to any future acquirer of DBV Technologies or his/her employing company or the business in which he/she is working within the duration of the Plan. This personal information shall be retained for the time required for the completion of the Plan and for the purposes of the management of the shareholder's account, until he/she sells all his/her DBV Technologies shares under the Plan, and thereafter for archiving purposes.

Every Participant will be able to exercise a right to access, to modify and to rectify, and as well as to delete (once he/she no longer holds any Shares under the Plan) any information relating to him/her. Furthermore, each Participant will have the right to restriction of processing and to object to processing as well as the right to data portability. The right of data portability shall allow the Participant to recover his/her data directly or to transfer them or have them transferred to another data controller (subject to legal limits). He/she will have a right to define the directives in relation to the registration, the removal and the communication of his/her personal data after his/her death.

In some countries, local regulations require the express consent of the Participant for the processing and transfer of his/her personal data. In such a case, the Participant's consents, under the acceptance procedure, to the collection, use, storage and transfer of his/her personal data, within the framework of local law. Furthermore, local law may provide that he/she has the right to withdraw his/her consent for the processing of his/her personal data. However, his/her personal data is necessary for the processing of his/her participation to the Plan, the holding of his/her Shares under the Plan and the execution of all operations related to his/her investment. Accordingly, he/she will be able to exercise his/her right to withdraw his/her consent only when all the Shares held under the Plan have been sold.

The Company has appointed a data protection officer, who is responsible for compliance with this notice and can be contacted at the following address: dataprivacy@dbv-technologies.com

The Participant have the right to lodge a complaint with his/her supervisory authority (in France, the supervisory authority is the CNIL), concerning the protection of personal data.

EXECUTIVE AGREEMENT

This EXECUTIVE AGREEMENT (the “*Agreement*”) between DBV Technologies S.A. (the “*Company*”), and Daniel Tasse (the “*Executive*”) is effective as of November 29, 2018 (the “*Effective Date*”).

WITNESSETH:

WHEREAS, the Company desires the Executive to provide services to the Company as a corporate officer (*mandataire social*), and wishes to provide the Executive with certain compensation and benefits in return for such services; and

WHEREAS, the Executive wishes to be employed by the Company and to provide services to the Company in return for certain compensation and benefits;

NOW THEREFORE, in consideration of the foregoing, of the mutual promises contained herein and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **AT WILL EMPLOYMENT.** The Executive shall be employed at will, meaning that either the Company or the Executive may terminate this Agreement and the Executive’s employment at any time, for any reason or no reason, with or without Cause, subject to the terms and conditions of this Agreement. Any contrary representations that may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the “at-will” nature of the Executive’s employment with the Company, which may be changed only in an express written agreement signed by the Executive and a duly authorized officer of the Company. The Executive’s rights to any compensation following a termination shall be only as set forth in Section 10.

2. **POSITION & DUTIES.** The Executive shall serve as the Company’s Chief Executive Officer (Directeur Général) (“*CEO*”). As CEO, the Executive shall participate as a nonvoting invitee in the meetings of the Company’s Board of Directors (the “*Board*”) (at the Board’s discretion and invitation); provided that the Company shall use commercially reasonable efforts to ensure that, in compliance with French law (including French legal diversity requirements), at the Company’s 2019 annual general meeting of shareholders, the Company shall nominate Executive for election as a member of the Board and the Company shall also use commercially reasonable efforts to ensure that, in compliance with French law (including French legal diversity requirements), the Company shall continue to re-nominate Executive for re-election to the Board at each subsequent shareholder meeting as necessary to renew Executive’s term on the Board such that Executive will remain a member of the Board for the duration of his employment by the Company. The Executive shall have such other duties, authorities and responsibilities consistent with French law governing the duties of a directeur général, and those commensurate with the duties, authorities and responsibilities of persons in similar capacities in similarly sized companies and such other duties and responsibilities as the Board shall designate that are consistent with the Executive’s position as CEO. The Executive shall use his best efforts to perform faithfully and efficiently the duties and responsibilities assigned to the Executive hereunder and devote all of the Executive’s business time (excluding periods of vacation and other approved leaves of absence) to the performance of the Executive’s duties with the Company.

3. **LOCATION.** Unless the parties otherwise agree in writing, at all times during Executive's employment with the Company, the Executive shall split his time and perform services, as reasonably determined by Executive, in accordance with the Company's business needs and the permanent establishment guidelines between the Company's offices in New York, New York, Summit, New Jersey and the Company's offices in Montrouge and Bagneux, France *provided, however*, that the Company may from time to time require the Executive to travel temporarily to other locations (domestic and international) in connection with the Company's business.

4. **BASESALARY.** The Company agrees to pay the Executive a base salary (the "**Base Salary**") at an annual rate of \$600,000 (USD), payable in accordance with the regular payroll practices of the Company. The Executive's Base Salary shall be subject to review and adjustment from time to time by the Company in its sole discretion; provided that in no event shall it be decreased other than in connection with an across-the-board decrease in base salary applicable to all executive officers of the Company, so long as such decrease in base salary is not greater than the percentage decrease that is applicable to all other executive officers as part of such across-the-board decrease in base salary. The annual base salary as determined herein from time to time, including any increases thereon, shall constitute "Base Salary" for purposes of this Agreement.

5. **ANNUAL BONUS.** With respect to each full calendar year during Executive's employment with the Company (beginning in the year of the Effective Date), the Executive will be eligible to earn an annual performance bonus with a target amount of not less than sixty-five percent (65%) of the Base Salary (the "**Annual Bonus**"). The Annual Bonus will be based upon the Board's assessment of the Executive's performance and the Company's attainment of targeted goals as set by the Board in its sole discretion, but after consultation with Executive. The Annual Bonus, if any, will be subject to applicable payroll deductions and withholdings. Following the close of each calendar year, the Board will determine whether the Executive has earned the Annual Bonus, and the amount of any Annual Bonus (which, for clarity, actual performance may result in an Annual Bonus that becomes payable which is greater or less than such target amount noted above), based on the set criteria. No amount of the Annual Bonus is guaranteed, and, except as otherwise provided in this Agreement, the Executive must be a corporate officer (*mandataire social*) in good standing on the last day of the annual performance period for the Annual Bonus to be eligible to receive an Annual Bonus for the calendar year. Executive shall be eligible to receive a pro-rated Annual Bonus for 2018. The Annual Bonus, if earned, will be paid (i) within 30 days after the Company's annual general meeting of shareholders (the "**AGM**"), which is typically held in June of the calendar year immediately following the applicable calendar year for which the Annual Bonus is being measured; and (ii) only if and to the extent that the required shareholder vote, as per French "say-on-pay" regulations at each annual AGM is received; provided, that any such Annual Bonus shall be paid in the calendar year following the calendar year to which the performance period relates (and in no event later than December 31 of such calendar year).

6. EQUITY AWARDS. The Executive shall be eligible to participate in the Company's equity compensation program. Subject to Board approval, which shall occur as soon as reasonably practicable following the Executive's first day of employment with the Company, and subject to compliance with applicable French law, the Executive will initially be granted an option to purchase up to 350,000 ordinary shares of the Company as traded on the French Bourse for an exercise price equal to the fair market value determined of such shares on the date of grant (the date such options are granted the "Grant Date"), determined by taking a weighted average of the quoted closing selling price for the twenty (20) trading days immediately preceding the Grant Date. The options will begin vesting based on the date the Executive commences employment with the Company (the "Vesting Start Date") and will vest over four (4) years with 25% of the shares subject to the option vesting on the one year anniversary of the Vesting Start Date and the remaining 75% of the shares subject to the option shall vest in six substantially equal bi-annual installments following the first anniversary of the Grant Date vesting in equal half-year installments over the following thirty-six (36) months, subject to the Executive's continued employment with the Company through the applicable vesting dates. Additionally, Executive shall only be eligible to exercise the vested options granted pursuant to this Section 6 if (a) the Executive remains employed with the Company through the exercise date (subject to exceptions for Executive's death or Disability under French law; and further subject to the provisions of the DBV Technologies S.A. Nonqualified Stock Option Grant Notice (2018 Options) (the "**Option Agreement**")) and (b) the Company has obtained the marketing approval from the U.S. Food and Drug Administration of Viaskin Peanut prior to the exercise date. The option award described above will be governed by and subject to the terms and conditions of any associated stock option agreement required to be entered into by Executive and the Company. The Company shall use commercially reasonable efforts to obtain approval of its shareholders at the 2019 AGM to permit exercise of the vested options post-termination as set forth in the form of option agreement attached hereto at **Exhibit 1** (other than for Executive's death or Disability, which are not subject to such approval).

7. BENEFITS.

(a) **BENEFIT PLANS.** The Executive shall, in accordance with Company policy and the terms of the applicable Company benefit plan documents, be eligible to participate in any benefit plan or arrangement, including health, life and disability insurance, retirement plans and the like, that may be in effect from time to time and made available to the Company's senior management. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

(b) **VACATION.** The Executive shall be eligible to accrue vacation time at the rate of twenty-five (25) days per year in accordance with the Company's vacation policy. Vacation is to be taken at such intervals as shall be appropriate and consistent with the proper performance of the Executive's duties hereunder.

(c) **FINANCIAL PLANNING/TAX EQUALIZATION.** Executive acknowledges that he is responsible for his own personal tax advice and is not relying on the Company for any such advice. The Company shall submit for shareholder approval at the 2019 AGM a proposal for Company reimbursement to the Executive for tax and financial planning services incurred by the Executive for the duration of Executive's employment with the Company.

In addition, the Company shall submit for shareholder approval at the 2019 AGM a proposal for provision to Executive of tax equalization payments, if applicable, for the duration of Executive's employment to account for any tax liabilities that, due to foreign tax requirements, result an aggregate income tax liability that is greater than the income tax liability that Executive would have otherwise had if he were only subject to income tax in the United States for such period.

(d) **GENERAL EXPENSE REIMBURSEMENTS.** The Company will reimburse the Executive for all reasonable business expenses that the Executive incurs in performing the services hereunder pursuant to the Company's usual expense reimbursement policies and practices, following submission by the Executive of reasonable documentation thereof. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"): (i) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (ii) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (iii) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

8. CONFIDENTIALITY AND POST-EMPLOYMENT OBLIGATIONS. As a condition of employment, the Executive agrees to execute and abide by the Company's current form of Employee Confidential Information, Inventions Assignment, Non-Competition and Non-Solicitation Agreement ("**Confidentiality Agreement**"), which is attached hereto as **Exhibit 2** and which may be amended by the parties from time to time without regard to this Agreement by mutual consent between Executive and the Company. The Confidentiality Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

9. OUTSIDE ACTIVITIES DURING EMPLOYMENT. The Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by him to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise during his employment with the Company without the written consent of the Board; provided, however, that this limitation shall not apply to any equity interest that Executive has in a Company which stock is publicly traded so long as Executive does not own more than 5% of such equity and the foregoing limitation does not apply to Executive's ownership interest in the companies listed on the attached **Exhibit 3**. Except with the prior written consent of the Board, during his employment with the Company the Executive will not undertake or engage in any other employment, occupation or business enterprise, except for passive investments; provided, however, that this restriction does not apply to any transition services that Executive is providing to the company listed in Exhibit 3, so long as such transition services do not extend beyond March 31, 2019 and such responsibilities do not materially interfere with Executive's services to the Company under this Agreement. Notwithstanding the foregoing, nothing shall prevent the Executive from participating in charitable, civic, educational, professional, community or industry affairs or, with prior written approval of the Board, serving on the board of directors or advisory board of up to two other public companies (Exhibit 3 sets forth the boards for which Executive is a member as of the date of this Agreement and for which the Board has currently consented). The Board may, in its sole discretion, withdraw its consent to your service on the boards listed on Exhibit 3 should a conflict arise between that board service and your employment hereunder. Executive shall resign from other current directorships beyond this number, which resignations shall take effect at the end of the respective directorship terms, but in no case later than June 30, 2019; *provided that* all such permitted activities or services in this Section 9 do not (i) create a conflict with his employment hereunder; (ii) materially interfere with the performance of his duties; or (iii) violate the terms of the Confidentiality Agreement.

10. **TERMINATION OF EMPLOYMENT.** The parties acknowledge that Executive's employment relationship with the Company is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause. The provisions in this Section are contingent upon and subject to (i) shareholder approval at the 2019 AGM, and are not effective unless and until such shareholder approval is secured; and (ii) the French "say-on-pay" requirements. If, and only if, approved by the shareholders at the 2019 AGM, the provisions in this Section will govern the amount of compensation, if any, to be provided to Executive upon termination of employment. In no event do the provisions of this Section alter the at-will status of Executive's employment with the Company.

(a) **Performance Conditions.** In addition to the above requirements regarding shareholder approval, all severance payments under this Section are contingent upon and subject to the following performance conditions: [TBD]1.

(b) **Termination by the Company without Cause or for Good Reason.**

(i) The Company shall have the right to terminate Executive's employment with the Company pursuant to this Section 10(b) at any time, in accordance with Section 10(h), or without "Cause" (as defined in Section 10(c)(ii) below) by giving notice as described in Section 10(h) of this Agreement. A termination pursuant to Sections 10(f) below is not a termination without Cause for purposes of receiving the benefits described in this Section.

(ii) If the Company terminates Executive's employment at any time without Cause or Executive terminates his employment with the Company for "Good Reason" (as defined in Section 10(b)(vii) below) and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), then Executive shall be entitled to receive the Accrued Obligations (defined in Section 10(b)(iv) below). If Executive complies with the obligations in Section 10(b)(iii) below, Executive shall also be eligible to receive the following "**Severance Benefits:**"

A. The Company will pay Executive an amount equal to the sum of (x) 1.5 times Executive's then current Base Salary (ignoring any decrease that forms the basis of Executive's resignation for Good Reason, if applicable) and (y) the then current target Annual Bonus opportunity for the fiscal year in which the Separation from Service occurs, for twelve (12) months (the "**Severance Period**"), less all applicable withholdings and deductions ("**Severance**"), paid in substantially equal installments over the Severance Period, with the first payment paid within sixty (60) days following the date of Executive's Separation from Service (the "**Separation Date**") and include an amount for the period from Executive's Separation Date and the first payment date and the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter for the duration of the Severance Period.

1 Conditions to be discussed and agreed upon by parties following execution of this Agreement.

B. If Executive timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Executive's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the Separation Date until the earliest of: (x) eighteen (18) months following the Separation Date (the "**COBRA Severance Period**"); (y) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (z) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the Separation Date through the earlier of (x)-(z), (the "**COBRA Payment Period**"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, plus an additional amount to reflect the taxes on such payment so that on a net after-tax basis the amount received by Executive shall be equal to the monthly COBRA premium, subject to applicable tax withholding (such amount, the "**Special Severance Payment**"), for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(iii) Executive will be paid all of the Accrued Obligations on the Company's first payroll date after Executive's date of termination from employment or earlier if required by law. Executive shall receive the Severance Benefits pursuant to Section 10(b)(ii) of this Agreement if: (x) within sixty (60) days following the date of Executive's Separation from Service, he has signed and delivered to the Company a separation agreement containing an effective, general release of claims in favor of the Company and its affiliates and representatives, in a form presented by the Company (the "**Release**"), which form of Release shall be in substantially the form attached hereto as **Exhibit 4**, which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "**Release Effective Date**"); (w) if he holds any other positions with the Company, including a position on the Board, he resigns such position(s) to be effective no later than the date of Executive's Separation Date (or such other date as requested by the Board); (x) he returns all Company property; (y) he complies with his post-termination obligations under this Agreement and the Confidential Information Agreement; and (z) he complies with the terms of the Release, including without limitation any non-disparagement and confidentiality provisions contained in the Release. To the extent that any of the Severance Benefits are deferred compensation under Section 409A of the Code payable within the sixty (60) day period following the Executive's Separation Date, and are not otherwise exempt from the application of Section 409A, then, if the sixty (60) day period during which Executive may consider and sign the Release spans two calendar years, the payment of the Severance Benefits will not be made or begin until the later calendar year.

(iv) For purposes of this Agreement, "**Accrued Obligations**" are (w) any unpaid Base Salary through the date of termination and any accrued vacation; (x) any unpaid bonus earned with respect to any calendar year ending on or preceding the date of termination; (y) reimbursement for any unreimbursed expenses under Section 7(c), above incurred through the date of termination; and (z) all other payments and benefits to which the Executive may be entitled under applicable law, the terms of any applicable compensation arrangement or benefit, equity or perquisite plan or program or grant or this Agreement, including but not limited to any applicable insurance benefits and accrued and vested benefits under any retirement plan or nonqualified deferred compensation plan.

(v) The Severance Benefits provided to Executive pursuant to this Section 10(b) are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Company severance plan, policy or program.

(vi) Any damages caused by the termination of Executive's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Executive is eligible pursuant to Section 10(b)(ii) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

(vii) For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of any of the following events without Executive's written consent: (i) a material reduction in Executive's Base Salary, which for this purpose shall be deemed to be a reduction of at least 10% from the rate in effect prior to such reduction of Base Salary; (ii) a material reduction in the Executive's duties, authority and responsibilities relative to the Executive's duties, authority, and responsibilities in effect immediately prior to such reduction; (iii) a requirement that Executive no longer report to the Board, except that if a Change in Control (as defined below) occurs, for purposes of determining the board after the Change in Control it shall be Executive no longer reports directly to the board of the ultimate parent of the Company; (iv) a requirement that Executive relocate Executive's principal place of employment to a location more than fifty (50) miles from Summit, New Jersey and, for purposes of clarity, any requirement that Executive be required to move to within daily commuting proximity to the Company's French headquarters shall constitute Good Reason; or (v) a material breach of this Agreement by the Company; *provided, however*, that, any such termination by Executive shall only be deemed for Good Reason pursuant to this definition if: (1) Executive gives the Company written notice of his intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the "**Cure Period**"); (3) the Company has not, prior to receiving such notice from Executive, already informed Executive that his employment with the Company is being terminated and (4) Executive voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(c) Termination by the Company for Cause.

(i) Subject to Section 10(c)(ii) below, the Company shall have the right to terminate Executive's employment with the Company at any time for Cause by giving notice as described in Section 10(h) of this Agreement.

(ii) For purposes of this Agreement, “Cause” means first, the Executive’s conviction of any felony or any crime involving fraud or embezzlement under the laws of the United States or any state which conviction results in material harm to the reputation of the Company (which, for purpose of clarity, would exclude traffic offenses). Second, “Cause” means, as reasonably determined by the Board, Executive’s acts or omissions that constitute the following conduct: (w) fraud or gross negligence against the Company causing material injury to the Company; (x) the material violation of any material Company policy (including but not limited to its sexual harassment policy) or any statutory duty owed to the Company which, in either case, results in material harm to the Company after Executive is provided with a reasonable opportunity of not less than fifteen (15) days to cure, to the extent curable, from the date written notice thereof is given to Executive by the Company; (y) unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (z) refusal to comply with a lawful directive of the Board consistent with Executive’s position with the Company after Executive is provided with a reasonable opportunity of not less than fifteen (15) days to cure from the date notice thereof is given to Executive by the Company.

(iii) In the event Executive’s employment is terminated at any time for Cause, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, consistent with the Company’s standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

(d) Resignation by the Executive.

(i) Executive may resign from Executive’s employment with the Company at any time by giving notice as described in Section 10(h).

(ii) In the event Executive resigns from Executive’s employment with the Company other than for Good Reason, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company’s standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

(e) Termination Without Cause or for Good Reason In Connection with a Change in Control.

(i) If Executive’s employment by the Company is terminated by the Company (or its successor or parent) without Cause (and not due to Disability or death) or by Executive for Good Reason, in either case, within three (3) months before or on, or within twenty-four (24) months immediately following, a Change in Control (as defined in the Option Agreement), that constitutes a change in control event described in Treasury Regulation Sections 1.409A-3(i)(5), then: the Company shall pay or provide Executive with the same Severance Benefits described in Section 11(b)(ii), except that the amount payable in Section 11(b)(ii)(A) shall be paid to Executive in a lump sum within sixty (60) days following Executive’s Separation Date, unless Executive’s employment is terminated within three (3) months before the Change in Control in which case the severance shall be paid in installments as provided in Section 11(b)(ii)(A), and any remaining amount shall be converted into, and paid in, a lump sum on the date of the Change in Control, *provided that* Executive executes and does not revoke the Release and otherwise complies with the requirements of Section 10(b)(iii).

(f) Termination by Virtue of Death or Disability of the Executive.

(i) In the event of Executive's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll practices, provide to the Executive's legal representatives Executive's Accrued Obligations, including any life insurance benefits payable to Executive's beneficiary under the Company's group life insurance plan.

(ii) Subject to applicable law, the Company shall at all times have the right, upon written notice to Executive, to terminate this Agreement based on Executive's Disability (as defined below). Termination by the Company of Executive's employment based on "**Disability**" shall mean termination because the Executive has been unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for a period of six (6) consecutive months and following the end of such six (6) month period the Executive has been determined to be disabled under the Company's long-term disability benefit plan and is eligible to receive benefits under such plan. In the event Executive's employment is terminated based on the Executive's Disability after the end of such six (6) month period, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations and amounts owed to Executive under the Company's long-term disability plan.

(g) Effective Date of Termination.

(i) Termination of Executive's employment pursuant to this Agreement shall be effective on the earliest of:

A. thirty (30) days after the Company gives notice to Executive of Executive's termination with Cause, unless pursuant to Sections 10(c)(ii)(x) or 10(c)(ii)(z) in which case fifteen (15) days after notice if not cured or unless the Company specifies a later date, in which case, termination shall be effective as of such later date if not cured;

B. immediately upon the Executive's death;

C. thirty (30) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, *provided* that Executive has not returned to the full time performance of Executive's duties prior to such date;

D. thirty (30) days after the Executive gives written notice to the Company of Executive's resignation, *provided* that the Company may set a termination date at any time between the date of notice and the date of resignation, in which case the Executive's resignation shall be effective as of such other date. Executive will receive compensation through any required notice period;

E. for a termination for Good Reason, immediately after Executive's full satisfaction of the requirements of Section 10(b)(vii); or

F. thirty (30) days after the Company gives notice to Executive of Executive's termination without Cause.

G. In the event notice of a termination under subsections (i)(A), (C) and (F) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five (5) business days of the request in compliance with the requirements of Section 13 below. In the event of a termination for Cause, written confirmation shall specify the subsection(s) of the definition of Cause relied on to support the decision to terminate.

(h) **Effect of Termination.** Executive agrees that should the Executive's employment be terminated for any reason, Executive shall be deemed to have resigned from any and all positions with the Company and its subsidiaries, including any position on the Board.

(i) **Cooperation With Company After Termination of Employment.** For the period that you are receiving any Severance under this Agreement, Executive shall fully cooperate with the Company in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company; provided, that the Company shall reimburse Executive for any reasonable expenses incurred relating to such cooperation and such cooperation does not interfere with any subsequent employment of Executive by another employer.

11. **INDEMNIFICATION.** While serving as an executive of the Company and director on the Board and following termination of Executive's employment, Executive shall be covered by the Company's Directors and Officers Liability Insurance at levels no less favorable than existing directors and officers and will enter into the form of indemnification agreement used by the Company with its other directors and executive officers, which form is attached hereto as **Exhibit 5**.

12. **ASSIGNMENT.** This Agreement shall be binding upon and inure to the benefit of the Executive and the Executive's heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of the Executive's duties under this Agreement, neither this Agreement nor any rights or obligations under this Agreement shall be assignable by the Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives. Any such successor or assign of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all, or substantially all, of the outstanding shares of the Company.

13. **NOTICE.** For the purpose of this Agreement, notices and all other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) on the date of delivery if delivered by hand, (b) on the date of transmission, if delivered by e-mail, (c) on the first business day following the date of deposit if delivered by guaranteed overnight delivery service, or (d) on the fourth business day following the date delivered or mailed by United States registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Company:

Joan Schmidt
General Counsel
DBV Technologies S. A.
25 DeForest Avenue, Suite 203
Summit, NJ 07901
joan.schmidt@dbv-technologies.com

and a copy (which shall not constitute notice) shall also be sent to:

Marc Recht
Cooley LLP
500 Boylston St.
Boston, MA 02116
mrecht@cooley.com

If to the Executive:

To the most recent address of the Executive set forth in the personnel records of the Company, or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall be effective only upon receipt.

14. **SECTION HEADINGS; INCONSISTENCY.** The section headings used in this Agreement are included solely for convenience and shall not affect, or be used in connection with, the interpretation of this Agreement. If there is any inconsistency between this Agreement and any other agreement (including but not limited to any option, stock, long-term incentive or other equity award agreement), plan, program, policy or practice (collectively, "**Other Provision**") of the Company the terms of this Agreement shall control over such Other Provision.

15. **SEVERABILITY.** The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof.

16. **COUNTERPARTS.** This Agreement may be executed in counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instruments. One or more counterparts of this Agreement may be delivered by facsimile, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

17. **SECTION 409A.** It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's separation from service (determined in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h) to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon separation from service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments as required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's separation from service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit. Each installment of severance benefits is a separate "payment" for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). The Company makes no representations or warranties as to whether any payments under this Agreement are subject to Section 409A of the Code or exempt.

18. **ADDITIONAL LIMITATION.**

(a) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "**Aggregate Payments**"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not

below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(b) For purposes of this Section 18, the “*After Tax Amount*” means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive’s receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes

(c) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 18(a) shall be made by a nationally recognized accounting firm selected by the Company, and reasonably acceptable to the Executive (the “*Accounting Firm*”), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days prior to the date of the consummation of the transaction or at such earlier time as is reasonably requested by the Company or the Executive. All costs of the Accounting Firm shall be borne by the Company.

19. **REPRESENTATIONS.** The Executive represents and warrants to the Company that the Executive has the legal right to enter into this Agreement and to perform all of the obligations on the Executive’s part to be performed hereunder in accordance with its terms and that the Executive is not a party to any agreement or understanding, written or oral, which could prevent the Executive from entering into this Agreement or performing all of the Executive’s obligations hereunder. The Executive further represents and warrants that he has been advised to consult with an attorney and that he has been represented by the attorney of his choosing during the negotiation of this Agreement, that he has consulted with his attorney before executing this Agreement, that he has carefully read and fully understand all of the provisions of this Agreement and that he is voluntarily entering into this Agreement.

20. **WITHHOLDING.** The Company may withhold from any and all amounts payable under this Agreement such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

21. **SURVIVAL.** The respective obligations of, and benefits afforded to, the Company and the Executive which by their express terms or clear intent survive termination of the Executive's employment with the Company, including, without limitation, the provisions of Sections 8 and 10-28, inclusive, of this Agreement, will survive termination of the Executive's employment with the Company, and will remain in full force and effect according to their terms.

22. **AGREEMENT OF THE PARTIES.** The language used in this Agreement will be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction will be applied against any party hereto. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement. Neither the Executive nor the Company shall be entitled to any presumption in connection with any determination made hereunder in connection with any arbitration, judicial or administrative proceeding relating to or arising under this Agreement.

23. **INTEGRATION.** This Agreement, including the Confidentiality Agreement, contains the complete, final and exclusive agreement of the parties relating to the terms and conditions of the Executive's employment and the termination of the Executive's employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the parties.

24. **AMENDMENT.** This Agreement cannot be amended or modified except by a written agreement signed by the Executive and a duly authorized officer of the Company.

25. **WAIVER.** No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the party against whom the waiver is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

26. **CHOICE OF LAW.** This Agreement shall be construed and interpreted in accordance with the internal laws of the State of New Jersey without regard to its conflict of laws principles. The Parties acknowledge that this Agreement contains the terms and conditions of services of the Executive as corporate officer (*mandataire social*) of the Company as such function is defined and regulated under the French Code of Commerce (*Code de commerce*) and shall not constitute, or be construed as, an employment agreement as defined by the French Labor Code (*Code du travail*).

27. **DISPUTE RESOLUTION.** To ensure the rapid and economical resolution of disputes that may arise in connection with the Executive's employment with the Company, the Executive and the Company both agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, the Executive's employment with the Company, or the termination of the Executive's employment from the Company, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted in Newark, New Jersey by JAMS, Inc. ("**JAMS**") or its successors. **Both the Executive and the Company**

acknowledge that by agreeing to this arbitration procedure, each waives the right to resolve any such dispute through a trial by jury or judge or administrative proceeding. Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which can be found at [HTTP://WWW.JAMSADR.COM/RULES-CLAUSES/](http://www.jamsadr.com/rules-clauses/), and which will be provided to the Executive upon request. The arbitrator shall be as mutually agreed between the Company and Executive. In any such proceeding, the arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (ii) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. The Executive and the Company each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law; *provided, however*, that in no event shall the arbitrator be empowered to hear or determine any class or collective claim of any type. Nothing in this Agreement is intended to prevent either the Company or the Executive from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. The Company shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration.

28. **LEGAL FEES.** In the event that there is a dispute under the terms of this Agreement, each party shall be responsible for its own legal fees and expenses, except that if Executive is successful on a dispute concerning a material issue hereunder, the Company shall reimburse to the Executive the legal fees and expenses incurred by the Executive in such dispute.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, effective as of the date first written above.

DBV Technologies S.A.

By: /s/ Pierre-Henri Benhamou
Pierre-Henri Benhamou
Co-founder, Chairman, Chief Executive Officer

Date: 15 Nov 2018

Daniel Tassé

/s/ Daniel Tassé

Date: 11/15/2018

EXHIBIT 1
(Stock Option Award Agreement)

DBV TECHNOLOGIES S.A.
NONQUALIFIED STOCK OPTION GRANT NOTICE
(2018 OPTIONS)

The Combined Annual General Meeting of Shareholders of DBV Technologies (the “**Company**”) of June 22, 2018 (the “**Annual General Meeting**”) authorized the Company’s Board of Directors (the “**Board**”) to grant options giving entitlement to shares of the Company to the persons that it may name from among the members of staff and officers of the Company and of companies associated with it subject to the terms of Article L.225-180 of the French Commercial Code.

Pursuant to this authorization, the Board decided at its meeting of June 22, 2018, the policy for allocation of Stock options to employees and Corporate Officers of the subsidiaries outside France according to their grade and the main characteristics of an options plan conferring the entitlement to subscribe to shares of the Company, known as “*DBV Technologies S.A. Stock Option Agreement*”. The Board delegated all power to the Chairman & CEO and to the Deputy CEO for the purpose of implementing this policy including the certification of the allocation decision upon the 15th of the month following the effective date of employment or an employment contract, the purchase price for options and the numbers of shares allocated to each Optionee.

Pursuant to this delegation, the Company hereby grants to the Optionee named below an option (the “**Stock Option**”) to purchase/subscribe on or prior to the Expiration Date specified below all or part of the number of shares of the Company’s Ordinary Shares, €0.10 nominal value per share (each, a “**Share**”), specified below at the Option Exercise Price per Share specified below subject to the terms and conditions set forth herein, in the attached Stock Option Agreement and Plan (the “**Agreement and Plan**”), all of which are incorporated herein in their entirety. This Stock Option is not intended to be an “incentive stock option” under Section 422 of the Internal Revenue Code of 1986, as amended, with respect to Optionees who are US tax residents.

Name of Optionee:	<u>Daniel Tasse</u>	(the “ Optionee ”)
No. of Options:	<u>350,000</u>	
No. of Shares:	<u>350,000</u>	
Grant Date:	<u></u>	<u>1</u>
Expiration Date:	<u></u>	(the “ Expiration Date ”) ²
Option Exercise Price/Share:	<u>€</u>	(the “ Option Exercise Price ”) ³

Vesting Schedule: 25 percent of the Shares subject to this Stock Option shall vest on [November 29, 2019] (the “**Vesting Date**”), subject to the Optionee’s Continuous Service through such date. Thereafter, the remaining 75 percent of the Shares shall vest in six substantially equal bi-annual installments following the first anniversary of the Vesting Date, subject to the Optionee’s Continuous Service through each such date, as set forth in the Agreement and Plan.

- 1 Grant Date will generally be the date following the Optionee’s commencement date that the Board approves the award.
- 2 Insert date that is 10 years from Grant Date.
- 3 Shall equal the closing price of the share on the Euronext Paris on the day that the Grant is recorded, but will not be less than the average of the share prices quoted over the 20 trading days preceding the date of said grant.

Exercise conditions: Notwithstanding the vesting schedule, no portion of this this Stock Option shall be exercisable unless the Company has obtained the marketing approval from US Food and Drug Administration (U.S. FDA) of Viaskin Peanut and Optionee has remained in Continuous Service through such date. Further, subject to Section 6 of the Agreement and Plan, Optionee must remain in Continuous Service through the applicable date of exercise.

Additional Terms/Acknowledgements: Optionee acknowledges receipt of, and understands and agrees to, this Grant Notice (as defined in this Agreement and Plan), this Agreement and Plan. Optionee acknowledges and agrees that this Grant Notice and this Agreement and Plan may not be modified, amended or revised except as provided herein. Optionee further acknowledges that as of the Date of Grant, this Grant Notice and this Agreement and Plan set forth the entire understanding between Optionee and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionee or (ii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

This Grant Notice is not to be interpreted as a guarantee or contract of Continuous Service (as defined in this Agreement and Plan).

By accepting this option, Optionee consents to receive such documents by electronic delivery and to participate in this Agreement and Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

DBV TECHNOLOGIES, S.A.

OPTIONEE:

By: _____ /s/ _____
Signature

_____ /s/ _____
Signature

Title: Deputy CEO
Date: November 15, 2018

Date: November 15, 2018

DBV TECHNOLOGIES S.A.
STOCK OPTION AGREEMENT AND PLAN

Pursuant to the Stock Option grant notice (the “**Grant Notice**”) and this Stock Option agreement (this “**Agreement and Plan**”), DBV Technologies (the “**Company**”) has granted Optionee an option (the “**Stock Option**”) under this Agreement and Plan referenced in the Grant Notice to purchase/subscribe the number of shares of the Company’s Ordinary Shares, €0.10 nominal value per share (each, a “**Share**”) indicated in the Grant Notice at the exercise price indicated in the Grant Notice. The Stock Option is granted to the Optionee effective as of the date of grant set forth in the Grant Notice (the “**Grant Date**”). Capitalized terms in this Agreement shall have the meaning specified in the Grant Notice unless a different meaning is specified herein.

The details of the Stock Option and this Agreement and Plan generally, in addition to those set forth in the Grant Notice, are as follows:

1. Legal Framework.

(a) The Combined Annual General Meeting of Shareholders of the Company of June 22, 2018 (the “**Annual General Meeting**”) authorized the Board to grant options to purchase and/or subscribe Shares to the persons that it may name from time-to-time among the members of staff and officers of the Company and of companies associated with it subject to the terms of Article L.225-180 of the French Commercial Code (the “**French Code**”). This authorization was given for a period of 18 months from the Annual General Meeting, under the provisions of Articles L.225-177 *et seq.* of the French Code.

(b) This Agreement and Plan and this Stock Option shall be administered by the Board. The Board may change the details of this Agreement and Plan and this Stock Option (including the Grant Notice) (i) if it considers that the change is appropriate and has no significant negative impact on the interests of the Optionees or (ii) with the agreement of the Optionees concerned. More generally, in case of a change in the legislation, regulations or accounting standards, or a change in the interpretation of such provision, particularly relating to the tax or social security arrangements for the allocation or exercise of options, the terms and conditions for the options under this Agreement and Plan, including this Stock Option, may be amended by the Board at its discretion, to respond to this change as it sees fit. By way of example, the Board might decide to shorten or extend the exercise period, or to introduce a mandatory retention period.

(c) The Board will have the power, subject to, and within the limitations of, the express provisions of this Agreement and Plan: (i) to construe and interpret this Agreement and Plan and this Stock Option (including the Grant Notice) and (ii) to settle all controversies regarding this Agreement and Plan and awards granted under it, including this Stock Option.

(d) The Board may delegate some or all of the administration of this Agreement and Plan to the Company’s Chief Executive Officer, provided such delegation complies with French law. The Board may retain the authority to concurrently administer this Agreement and Plan with the Chief Executive Officer and may, at any time, revert in the Board some or all of the powers previously delegated.

(e) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

2. Vesting. Subject to the provisions contained herein, the Stock Option will vest as provided in the Grant Notice. Vesting will cease upon the termination of Optionee's Continuous Service, unless otherwise provided below. Upon and subject to the occurrence of a Takeover, the Stock Options will be deemed 100% vested and exercisable.

The Stock Options are exercisable within a ten (10) year period as from the Grant Date and in accordance with the provisions of this Agreement and Plan.

3. Number of Shares and Exercise Price. The number of Shares subject to this Stock Option and the Option Exercise Price are set forth in the Grant Notice. As provided for in the Grant Notice, each Stock Option shall give entitlement to acquire/subscribe to one (1) Share, subject to adjustments provided for in Section 10 below.

For the avoidance of doubt, it is specified that the Option Exercise Price shall correspond to the price of the Shares on Euronext Paris on the Grant Date, but will not be less than the average of the share prices quoted over the twenty (20) trading days preceding the Grant Date.

4. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option and in accordance with the terms of this Stock Options, the Optionee may give written notice to the Company of his or her election to purchase/subscribe some or all of the Shares subject to this Stock Option purchasable/being available to subscription at the time of such notice. This notice shall specify the number of Shares to be purchased/subscribed.

(b) Payment of the purchase price for the Shares may be made in cash, by certified or bank check or other instrument acceptable to the Board or, if allowable under applicable law, by way of offsetting receivables held by the Optionee against the Company.

(c) Payment instruments will be received subject to collection. The transfer to the Optionee on the records of the Company or of the transfer agent of the Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase/subscription price for the Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in this Agreement and Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Shares to be purchased/subscribed pursuant to the exercise of Stock Options under this Agreement and Plan and any subsequent resale of the Shares will be in compliance with applicable laws and regulations.

(d) The Shares purchased/subscribed upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Board with all requirements under this Agreement and Plan, applicable laws or regulations in connection with such transfer and with the requirements hereof. The determination of the Board as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Shares subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such Shares. Such Shares shall be freely transferable once the Stock Option has been exercised, subject to compliance with the applicable legal and regulatory provisions as set forth in Sections 7 and 13 below.

(e) Notwithstanding any other provision hereof or of this Agreement and Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof, unless allowable under applicable law.

5. Exercise Conditions. The exercise of this Stock Option is subject to:

(a) the existence of Continuous Service at the date of exercise of the said Stock Option in accordance with this Agreement and Plan (subject to the provisions of Section 6 below), and

(b) the Company having obtained the marketing approval from US Food and Drug Administration (U.S. FDA) of Viaskin Peanut. This condition shall be determined by the Board of Directors (the "**Performance Condition**").

6. Termination of Continuous Service. The exercise of the Stock Option is subject to the existence of Continuous Service at the date of exercise of the said Stock Option in accordance with this Agreement and Plan, subject to the exceptions set forth in this Section 6. If the Optionee's Continuous Service is terminated for death or Disability, the period within which to exercise the Stock Option shall be as set forth below:

(a) Termination Due to Death. If the Optionee's Continuous Service terminates by reason of the Optionee's death, any portion of this Stock Option shall be fully vested, and may thereafter be exercised (subject to completion of the Performance Condition at the date of exercise) by the Optionee's heir(s) for a period of six (6) months from the date of death, or until the Expiration Date, if earlier.

(b) Termination Due to Disability. If the Optionee's Continuous Service terminates by reason of the Optionee's Disability, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may thereafter be exercised by the Optionee (subject to completion of the Performance Condition at the date of exercise) for a period of six (6) months from the termination of Optionee's Continuous Service by reason of the Optionee's Disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not vested on the date the Optionee's Continuous Service terminates by reason of the Optionee's Disability shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Continuous Service terminates for Cause, any portion of this Stock Option outstanding on such termination date according to the vesting schedule set forth in Section 2, to the extent exercisable on such termination date, shall terminate immediately and be of no further force and effect. Any portion of this Stock Option that is not vested on such termination date shall also terminate immediately and be of no further force and effect.

(d) Termination without Cause; Termination for Good Reason. If the Optionee's Continuous Service is terminated by the Group Companies without Cause or by the Optionee with Good Reason, then, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may be exercised, to the extent exercisable on the date of termination (subject to completion of the Performance Condition), for a period of thirty (30) days following the date of such termination (or, to the extent applicable, such longer period specified in (f), below), provided that if an exercise suspension period (as described in Section 7, below) occurs at any time during such period, then the vested portion of this Stock Option will not expire until it has been exercisable for an aggregate period of thirty (30) days following such termination of Continuous Service, provided that in no event will this Stock Option be exercisable following the Expiration Date. Any portion of this Stock Option that is not vested on the date of termination shall terminate immediately and be of no further force or effect.

Further, following (and subject to) approval of the Company's shareholders at the 2019 Annual General Meeting, if the Optionee's Continuous Service is terminated for any of the reasons set forth in paragraphs (e) and (f), the period within which to exercise the Stock Option shall be as set forth below:

(e) Retirement. If the Optionee's Continuous Service terminates as a result of Retirement, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may thereafter be exercised (subject to completion of the Performance Condition) by the Optionee at any time before the Expiration Date of the Stock Option. Any portion of this Stock Option that is not vested on the date of Retirement shall continue to vest in accordance with the vesting schedule set forth in Section 2 and become exercisable after attainment of vesting (subject to completion of the Performance Condition) at any time before the Expiration Date of the Stock Option.

(f) Other Termination. If the Optionee's Continuous Service terminates for any reason (including a termination further to a Takeover) other than the Optionee's death, the Optionee's Disability, the Optionee's Termination for Cause or the Optionee's Retirement, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may be exercised, to the extent exercisable on the date of termination (subject to completion of the Performance Condition), for a period of (i) ninety (90) days from the date of termination if the Optionee is a U.S. employee of a Group Company or (ii) six (6) months from the date of termination for Optionee other than U.S. employee of a Group Company, or until the Expiration Date, if earlier. Any portion of this Stock Option that is not vested on the date of termination shall terminate immediately and be of no further force or effect.

For the avoidance of doubt, the date of termination of the Optionee's Continuous Service shall be as follows, it being specified that such date of termination may be adapted from time to time depending on any local applicable laws:

- in the event of death or Disability, the date of such Optionee's death or determination of Disability;
- in the event of resignation of the contract of employment or the corporate mandate, with effect from the day that the Group Company receives the letter of resignation from the Optionee or the day that it is handed to an authorized representative of the Group Company;
- in the event of dismissal, with effect from the day that the relevant party receives the dismissal notification letter, notwithstanding (i) a notice period, whether or not completed; (ii) any challenge by the Optionee to their dismissal and/or the reasons for it; and (iii) any legal ruling that would challenge the grounds for the dismissal;
- in the event of contractual termination, with effect from the administrative approval of the termination agreement;
- in the event of the revocation of the corporate mandate, with effect from the day of the meeting of the executive body deciding on its revocation if the Optionee is in attendance, or, if he is not in attendance, from the date that notification of this decision is received, notwithstanding (i) a notice period, whether or not completed; (ii) any challenge by the Optionee to the revocation and/or the reasons for it; and (iii) any legal decision that would challenge the validity of the revocation;
- in the event of the non-renewal of the corporate mandate, with effect from the expiry date of the corporate mandate.

If the Optionee is a U.S. employee of a Group Company, the date of termination shall be as follows:

- in the event of death or Disability, the date of such Optionee's death or determination of Disability by the Company Group or its designee;
- in the event of resignation (or equivalent) by the Optionee, the date specified in any letter of resignation by the Optionee or such as earlier date as determined in its sole discretion by the Group Company in which the Optionee holds an employee or Director position at the date of termination;
- in the event of termination (dismissal, removal or equivalent) of the Optionee's Continuous Service by the Group Company in which the Optionee holds an employee or Director position, the date specified by such Group Company;
- in the event that there is a contract of employment or a corporate mandate between the Optionee and the Group Company in which the Optionee holds an employee or Director position, the date specified in such contract of employment or contract mandate for the relevant type of termination or as mutually agreed by the parties; or

- in the event of agreed termination (or equivalent), the date of execution of the termination agreement by all parties.

The Board's determination of the reason for termination of the Optionee's Continuous Service shall be conclusive and binding on the Optionee and his or her legal heirs.

7. Suspension of Exercise Rights.

(a) Notwithstanding anything in this Agreement and Plan, this Stock Option may not be exercised (i) for a period of 30 calendar days prior to the publication of the annual and half-yearly results, (ii) for a period of 15 calendar days prior to the publication of the quarterly revenue figures or (iii) when Optionee holds "inside information." For this purpose, "inside information" is any information which, if made public, could have a significant influence on the price determined in accordance with 7.1 of the Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse.

(b) In addition, the Board may also elect to temporarily suspend the right to exercise this Stock Option, upon occurrence of certain financial transactions involving the share capital of the Company and which require accurate prior knowledge of the number of issued shares composing the share capital of the Company. In such event, Optionee will be informed by letter of the date on which exercise is suspended and the date of resumption. This information shall be provided by non-recorded delivery, with seven days' advance notice.

(c) If the event the Optionee's Continuous Service terminates during any exercise suspension period, Optionee may exercise this Stock Option at the end of the suspension period (to the extent then exercisable and subject to completion of the Performance Condition) for an additional period that is equal to the term of the suspension (or if earlier, through the Expiration Date), without this period extending the term of the Stock Option past the Expiration Date.

8. Transferability. This Stock Option is not transferable and non-assignable as provided for in Article L.225-183 of the French Code, subject to the provisions of Section 6 (a) above.

9. Tax Withholding Obligations.

(a) At the time this Stock Option is exercised, in whole or in part, and at any time thereafter as requested by the Company, Optionee hereby authorizes withholding from payroll and any other amounts payable to Optionee, and otherwise agrees to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or a Subsidiary, if any, which arise in connection with the exercise of this Stock Option.

(b) Optionee may not exercise this Stock Option unless the tax withholding obligations of the Company and/or any Subsidiary are satisfied. Accordingly, Optionee may not be able to exercise this Stock Option when desired even though the option is vested, and the Company will have no obligation to issue a certificate for such Shares or otherwise enter Optionee's name as the stockholder of record on the books of the Company, unless such obligations are satisfied.

(c) Optionee hereby agrees that the Company does not have a duty to design or administer this Agreement and Plan or its other compensation programs in a manner that minimizes Optionee's tax liabilities. Optionee will not make any claim against the Company, or any of its officers, directors, employees, Subsidiaries or affiliates related to tax liabilities arising from this Stock Option or Optionee's other compensation and the Company encourages the Optionee to consult at his/her own expenses with his/her own tax adviser to determine the tax consequences applicable to him/her in relation to this Stock Option. In particular, in the event the Optionee is a US tax resident, Optionee acknowledges that this option is exempt from Section 409A of the Code only if the exercise price per share is at least equal to the "fair market value" per Share on the Grant Date and there is no other impermissible deferral of compensation associated with the option.

10. Adjustments for Changes in Capitalization. In the case of an event described in Article L.225-181 of the French Code, the Company shall take the necessary action to protect the interests of the Optionee beneficiaries under the conditions stipulated in Article L.228-99 of the French Code. For this purpose, the Company will take all the measures stipulated in Article L.228-99 of the French Code. In particular, it may adjust the number of Shares subject to this Stock Option and the Option Exercise Price under the conditions and following the procedures laid down by the regulatory provisions of the French Code for each scenario that qualifies for an adjustment. The Board's adjustments shall be final, binding and conclusive.

11. No Obligation to Continue Service. Neither the Company nor any Subsidiary is obligated by or as a result of this Agreement and Plan to continue the Optionee's Continuous Service and this Agreement and Plan shall not interfere in any way with the right of the Company or any subsidiary to terminate the employment or other service of the Optionee at any time or for any reason.

12. Data Privacy. In order to administer this Agreement and Plan and to implement or structure future equity grants, the Company, its Subsidiaries and affiliates and certain agents thereof (together, the "**Relevant Companies**") may process any and all personal or professional data, including but not limited to any identification number (excluding the social security number), home address and telephone number, date of birth and other information that is necessary or desirable for the administration of this Agreement and (the "**Relevant Information**"). By entering into this Agreement and Plan, the Optionee acknowledges being informed (i) of the legitimate interest of the Company to collect, process, register and disclose to the Relevant Companies all Relevant Information; (ii) that the Relevant Companies may store and transmit such information in electronic form; and (iii) that the Relevant Information may be transferred to any jurisdiction in which the Relevant Companies consider appropriate, being specified that where the concerned jurisdiction is not located within the European Union, the Company undertakes to take all relevant guarantees, either on the basis of an adequacy decision or, in the absence of such a decision, on the basis of appropriate safeguards (e.g. binding corporate rules or contractual clauses), whose copy can be made available upon request. The Relevant Information will be stored only for the required duration for the purposes of administering this Agreement and Plan and implementing or structuring future equity grants as well as, beyond, for the purposes of evidence and legal obligations for a period not exceeding the applicable statutory limitation periods. The Optionee shall have access to, and the right to change, delete, if any limit or object, subject to legitimate and compelling reasons, the Relevant Information. These rights can be exercised directly by notifying the Company under the conditions stated in Section 17 below.

13. Trading Policy Restrictions.

(a) Exercise of this Stock Option and the disposition of any Shares issued in connection therewith shall be subject to the Company's insider trading policies and procedures, and all applicable laws regarding insider trading, restriction on exercise and sale of the Shares as in effect and applicable to Optionee from time to time. In addition, Optionee acknowledges receipt of the Company's policy permitting certain individuals to sell shares and exercise options only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

(b) In accordance with the provisions of Article L.621-18-2 of the French Monetary and Financial Code, the exercise of this Stock Option and the disposition of any Shares issued in connection therewith by a corporate officer or any person who has, within the Company, (i) the power to take management decisions regarding its development and strategy, (ii) regular access to inside information relating directly or indirectly to the Company, requires that the French *Autorité des Marchés Financiers* be informed, with a copy sent to the Company, within the timeframe laid down in the regulations currently in force (currently within five (5) trading days).

14. Claw Back. For US employees, any amounts paid (or shares of Common Stock granted) under this Stock Option will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any plan of or agreement with the Company.

15. Governing Law. This Agreement and Plan are subject to and must be interpreted according to the provisions of French law and any dispute relating thereto will fall under the exclusive competence of the court with appellate jurisdiction for the location of the Company's registered office.

16. Certain Definitions.

(a) **"Board"** means the Board of Directors of the Company, or as context requires, the group then responsible for administration of this Stock Option and/ this Agreement and Plan at the relevant time (i.e., either the Board or a committee or committees of the Board, as applicable) or delegated relevant administrative authority with respect to this Agreement and Plan and/or this Stock Option.

(b) **“Cause”** shall mean, unless otherwise provided in an employment agreement between a Group Company and the Optionee, as determination by the Group Company to dismiss the Optionee as a result of the Optionee’s gross negligence or willful misconduct. Such definition may be adapted from time to time depending on any local applicable laws defining “cause” in terms comparable to Cause.

For the sake of clarity, it is specified that for:

- U.S. employees, “Cause” shall mean, (i) the Optionee’s dishonest statements or acts with respect to the Company or any Subsidiary or affiliate of the Company, or any of the Company or any Subsidiary’s current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) the Optionee’s commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Optionee’s gross negligence or willful misconduct with respect to the Company or any Subsidiary or affiliate of the Company; or (iv) the Optionee’s material violation of any provision of any agreement(s) between the Optionee and the Company (or any Subsidiary of the Company) relating to noncompetition, nondisclosure and/or assignment of inventions;
- French employee, “Cause” shall mean the Optionee’s (i) gross negligence *“faute grave”* as this notion is determined by the labor division of the French *Cour de cassation* or (ii) willful misconduct *“faute lourde”* as this notion is determined by the labor division of the French *Cour de cassation*.

(c) **“Code”** means the U.S. Internal Revenue Code of 1986, as amended

(d) **“Continuous Service”** means that the Optionee’s service with a Group Company, whether as an employee or Director, is not interrupted or terminated. A change in the capacity in which the Optionee renders service to a Group Company as an employee or Director or a change in the entity for which the Optionee renders such service, provided that there is no interruption or termination of the Optionee’s service with the a Group Company, will not terminate the Optionee’s Continuous Service; *provided, however*, that if the entity for which the Optionee is rendering services ceases to qualify as a Group Company, as determined by the Board, in its sole discretion, the Optionee’s Continuous Service will be considered to have terminated on the date such entity ceases to qualify as a Group Company. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, a Subsidiary, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Optionee, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of “separation from service” as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(e) “**Director**” shall mean a member of the Board of Directors of the Company.

(f) “**Disability**” means, unless otherwise provided in an employment agreement between a Group Company and the Optionee, the inability of the Optionee to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. Such definition may be adapted from time to time depending on any local applicable laws defining “disability” in terms comparable to Disability.

For the sake of clarity, it is specified that for (i) U.S. employees, Disability shall have the meaning ascribed to it in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code or as determined under any applicable company long-term disability plan and (ii) French employees, Disability shall have the meaning ascribed to it in Article L.341.4 of the French Social Security Code.

(g) “**Good Reason**” shall have the meaning provided in that certain Executive Agreement, effective as of November 29, 2018, by and between the Company and the Optionee.

(h) “**Group**” means the Company and its Subsidiaries.

(i) “**Group Company**” means a company of the Group.

(j) “**Retirement**” means (i), if the Optionee is a U.S. employee of a Group Company, termination of Continuous Service after attainment of age 62 or (ii), in respect of Optionee other than U.S. employee of a Group Company, termination of Continuous Service due to retirement as decided by the Optionee or by the Group Company as provided for under any applicable law.

(k) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than 50 percent of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50 percent.

(l) “**Takeover**” has the meaning provided in Article L.233-3 of the French Code. Such definition may be adapted from time to time depending on any local applicable laws defining “takeover” in terms comparable to Takeover. For the avoidance of doubt, it is specified that a Takeover for a U.S. Optionee also complies with the definition of “change of control” under Section 409A of the Code.

17. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing. The Company may, in its sole discretion, decide to deliver any documents related to participation in this Agreement and Plan and this Stock Option by electronic means or to request the Optionee's consent to participate in this Agreement and Plan by electronic means. By accepting this Stock Option, the Optionee consent to receive such documents by electronic delivery and to participate hereunder through an on-line or electronic system established and maintained by the Company or another third party designated by the Company from time-to-time.

EXHIBIT 2
(Employee Confidential Information, Inventions Assignment, Non-Competition and Non-Solicitation Agreement)

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

In consideration of my employment or continued employment by DBV Technologies S.A., its subsidiaries, parents, affiliates, successors and assigns (together, the “*Company*”), the compensation paid to me now and during my employment with the Company, and the Company’s agreement to provide me with access to its Confidential Information (as defined below), I hereby enter into this Employee Confidential Information and Invention Assignment Agreement (the “*Agreement*”) and agree as follows:

1. CONFIDENTIAL INFORMATION PROTECTIONS.

1.1 Recognition of the Company’s Rights; Nondisclosure. I understand and acknowledge that my employment by the Company creates a relationship of confidence and trust with respect to the Company’s Confidential Information (as defined below) and that the Company has a protectable interest therein. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon, or publish any of the Company’s Confidential Information that I obtain during my employment with the Company, except as such disclosure, use or publication may be required in connection with my work for the Company, or unless an officer of the Company expressly authorizes such disclosure. I will obtain the Company’s written approval before publishing or submitting for publication any material (written, oral, or otherwise) that discloses and/or incorporates any Confidential Information. I hereby assign to the Company any rights I may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole and exclusive property of the Company and its assigns. I will take all reasonable precautions to prevent the inadvertent accidental disclosure of Confidential Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

1.2 Confidential Information. The term “*Confidential Information*” shall mean any and all confidential knowledge, data or information of the Company. By way of illustration but not limitation, “*Confidential Information*” includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, software in source or object code versions, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Intellectual Property

Rights therein (collectively, “*Inventions*”); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business strategies, operational plans, financing and capital-raising plans, activities and agreements, internal services and operational manuals, methods of conducting Company business, suppliers and supplier information, and purchasing; (c) information regarding Customers of the Company (as the term “*Customer*” is defined below), including Customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by the Company, proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided to Customers of the Company and other nonpublic information relating to Customers; (d) non-public information regarding any of the Company’s business partners and their services, including proposals, bids, contracts and their contents, the type and quantity of products and services received by the Company, and other non-public information relating to business partners; (e) non-public information regarding personnel, employee lists, and compensation; and (f) any other non-public information of the Company which a competitor of the Company could use to the competitive disadvantage of the Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to employment with the Company, which I lawfully obtained after my employment with the Company, or which is generally known to the public, in the trade or in the industry through no breach of this Agreement or other improper act or omission by me.

1.3 Third Party Information. I understand, in addition, that the Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data or information (“*Third Party Information*”) subject to a duty on the Company’s part to maintain the confidentiality of such information and to use it only for certain limited purposes. During my employment and thereafter, I will hold Third Party

Information that I obtain during my employment with the Company in confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for the Company) or use, except in connection with my work for the Company, Third Party Information unless expressly authorized by an officer of the Company in writing. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to employment with the Company, which I lawfully obtained after my employment with the Company, or which is generally known to the public, in the trade or in the industry through no breach of this Agreement or other improper act or omission by me.

1.4 Term of Nondisclosure Restrictions. I understand that Confidential Information and Third Party Information is never to be used or disclosed by me. If a temporal limitation on my obligation not to use or disclose such information is required under applicable law, and the Agreement or its restriction(s) cannot otherwise be enforced, I agree and the Company agrees that the two (2) year period after the date my employment ends will be the temporal limitation relevant to the contested restriction; *provided, however*, that this sentence will not apply to trade secrets protected without temporal limitation under applicable law.

1.5 No Improper Use of Information of Prior Employers and Others. During my employment by the Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

2. ASSIGNMENTS OF INVENTIONS.

2.1 Definitions. As used in this Agreement, the term ***“Intellectual Property Rights”*** means all trade secrets, Copyrights, trademarks, mask work rights, patents and other intellectual property rights recognized by the laws of any jurisdiction or country; the term ***“Copyright”*** means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (as a literary, musical, or artistic work) recognized by the laws of any jurisdiction or country; and the term ***“Moral Rights”*** means all paternity, integrity, disclosure, withdrawal, special and any other similar rights recognized by the laws of any jurisdiction or country.

2.2 Excluded Inventions and Other Inventions. Attached hereto as **Exhibit A** is a list describing all existing Inventions, if any, that may relate to the Company’s business or actual or demonstrably anticipated research or development and that were made by me or acquired by me prior to the commencement of my employment with, and which are not to be assigned to, the Company (***“Excluded Inventions”***). If no such list is attached, I represent and agree that it is because I have no rights in any existing Inventions that may relate to the Company’s business or actual or demonstrably anticipated research or development. For purposes of this Agreement, ***“Other Inventions”*** means Inventions in which I have or may have an interest, as of the commencement of my employment or thereafter, other than Company Inventions (defined below) and Excluded Inventions. I acknowledge and agree that if I use any Excluded Inventions or any Other Inventions in the scope of my employment, or if I include any Excluded Inventions or Other Inventions in any product or service of the Company, or if my rights in any Excluded Inventions or Other Inventions may block or interfere with, or may otherwise be required for, the exercise by the Company of any rights assigned to the Company under this Agreement, I will immediately so notify the Company in writing.

2.3 Assignment of Company Inventions. Inventions assigned to the Company, or to a third party as directed by the Company pursuant to Section 2.6, are referred to in this Agreement as ***“Company Inventions.”*** Subject to Section 2.4 (Unassigned or Nonassignable Inventions) and except for Excluded Inventions set forth in **Exhibit A** and Other Inventions, I hereby assign to the Company all my right, title, and interest in and to any and all Company Inventions (and all Intellectual Property Rights with respect thereto) made, conceived, reduced to practice, or learned by me, either alone or with others, during the period of my employment by the Company, which I developed on Company time or using the Company’s equipment, supplies, facilities, trade secrets or Confidential Information. To the extent required by applicable Copyright laws, I agree to assign in the future (when any copyrightable Inventions are first fixed in a tangible medium of expression) my Copyright rights in and to such Inventions. Any assignment of the Company Inventions (and all Intellectual Property Rights with respect thereto) hereunder includes an assignment of all Moral Rights. To the extent such Moral Rights cannot be assigned to the Company and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against the Company or related to the Company’s Customers, with respect to such rights. I further acknowledge and agree that neither my successors-in-interest nor legal heirs retain any Moral Rights in any Company Inventions (and any Intellectual Property Rights with respect thereto).

2.4 Unassigned or Nonassignable Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that I developed entirely on my own time without using the Company's equipment, supplies, facilities, trade secrets or Confidential Information, except for those Inventions that either (i) relate to the Company's actual business, research or development, or (ii) result from or are connected with work performed by me for the Company. In addition, this Agreement does not apply to any Invention which qualifies fully for protection from assignment to the Company under any specifically applicable state law, regulation, rule or public policy ("**Specific Inventions Law**").

2.5 Obligation to Keep the Company Informed. During the period of my employment and for one (1) year after termination of my employment, I will promptly and fully disclose to the Company in writing all Inventions authored, conceived, or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to the Company all patent applications filed by me or on my behalf within one (1) year after termination of employment. At the time of each such disclosure, I will advise the Company in writing of any Inventions that I believe fully qualify for protection under the provisions of any applicable Specific Inventions Law; and I will at that time provide to the Company in writing all evidence necessary to substantiate that belief. The Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any Inventions or information disclosed in writing to the Company pursuant to this Agreement relating to Inventions. I will preserve the confidentiality of any Invention that does not fully qualify for protection under a Specific Inventions Law.

2.6 Government or Third Party. I agree that, as directed by the Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

2.7 Ownership of Work Product.

(a) I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by Copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

(b) I agree that the Company will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to the Company all right, title, and interest worldwide in and to such work product. I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for the Company.

2.8 Enforcement of Intellectual Property Rights and Assistance. I will assist the Company in every proper way to obtain, and from time to time enforce, United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Intellectual Property Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Intellectual Property Rights to the Company or its designee, including the United States or any third party designated by the Company. My obligation to assist the Company with respect to Intellectual Property Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but the Company will compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance. In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in this paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and on my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned under this Agreement to the Company.

2.9 Incorporation of Software Code. I agree that I will not incorporate into any Company software or otherwise deliver to the Company any software code licensed under the GNU General Public License or Lesser General Public License or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by the Company except in strict compliance with the Company's policies regarding the use of such software.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by the Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at the Company, which records will be available to and remain the sole property of the Company at all times.

4. DUTY OF LOYALTY DURING EMPLOYMENT. I agree that during the period of my employment by the Company, I will not, without the Company's express written consent or as otherwise permitted in my Executive Agreement, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by the Company.

5. NO SOLICITATION OF EMPLOYEES, CONSULTANTS, CONTRACTORS, OR CUSTOMERS. Except as modified by Section 10.3 below, I agree that during the period of my employment and for the one (1) year period after the termination of my relationship with the Company for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of the Company:

5.1 hire, recruit, solicit, induce, encourage, or participate in hiring, recruiting, soliciting, inducing or encouraging any person known to me to be an employee, consultant, or independent contractor of the Company to terminate his or her relationship with the Company, even if I did not initiate the discussion or seek out the contact;

5.2 solicit, induce, encourage or attempt to solicit, induce, or encourage any Customer (as defined below), to terminate, diminish, or otherwise alter in a manner harmful to the Company, its relationship with the Company;

5.3 perform, provide or attempt to perform or provide any Conflicting Services for a Customer; or

5.4 solicit, induce, encourage or attempt to solicit, induce, or encourage, any franchisee, joint venture, supplier, vendor or contractor who conducted business with the Company at any time during the two year period preceding the termination of my employment with the Company, to terminate or adversely modify any business relationship with the Company or not to proceed with, or enter into, any business relationship with the Company, nor shall I otherwise interfere with any business relationship between the Company and any such franchisee, joint venture, supplier, vendor or contractor.

I agree that for purposes of this Agreement, a "**Customer**" is any person or entity who or which used the Company's services, or which I have actual knowledge as a person or entity in the Company's sales pipeline, at any time during the two-year period preceding the termination of my employment with the Company. I acknowledge and agree that the Customers did not use the Company's services solely as a result of my efforts, and that the efforts of other Company personnel and resources are responsible for the Company's relationship with the Customers. I further acknowledge and agree that the identity of the Customers is not readily ascertainable or discoverable through public sources, and that the Company's list of Customers was cultivated with great effort and secured through the expenditure of considerable time and money by the Company.

6. NON-COMPETE PROVISION.

6.1 Except as modified by Section 10.3 below, I agree that during the period of my employment and for the one (1) year period after the termination of my relationship with the Company for any reason, including but not limited to voluntary termination by me or involuntary termination by the Company, I will not, whether paid or not: (i) serve as a partner, principal, licensor, licensee, employee, consultant, officer, director, manager, agent, affiliate, representative, advisor, promoter, associate, investor, or otherwise for, (ii) directly or indirectly, own, purchase, organize or take preparatory steps for the organization of, or (iii) build, design, finance, acquire, lease, operate, manage, control, invest in, work or consult for or otherwise join, participate in or affiliate myself with, any business whose business, products or operations are in any respect involved in Conflicting Services (defined below) anywhere in the Restricted Territory (defined below).

Should I obtain other employment during my employment with the Company or within twelve (12) months immediately following the termination of my relationship with the Company, I agree to provide written notification to the Company as to the name and address of my new employer, the position that I expect to hold, and a general description of my duties and responsibilities, at least three (3) business days prior to starting such employment.

6.2 I agree that nothing herein shall prohibit me from purchasing or owning less than five percent (5%) of the publicly traded securities of any corporation, provided that such ownership represents a passive investment and that I am not a controlling person of, or a member of a group that controls, such corporation.

6.3 I agree that for purposes of this Agreement, "**Conflicting Services**" means any business in which the Company is primarily engaged at any time during the two-year period prior to the date of the termination of my relationship with the Company, or any primary service that the Company provides at any time during the two-year period prior to the date of the termination of my relationship with the Company.

6.4 I agree that for purposes of this Agreement, "**Restricted Territory**" means (i) all states within the United States in which I primarily perform services for the Company; and (ii) any other countries from which the Company provided goods or services, had Customers, or otherwise conducted business at any time during the two-year period prior to the date of the termination of my relationship with the Company.

7. REASONABLENESS OF RESTRICTIONS.

7.1 I acknowledge that I will derive significant value from the Company's agreement to provide me with Company Confidential Information to enable me to optimize the performance of my duties to the Company. I further acknowledge that my fulfillment of the obligations contained in this Agreement, including, but not limited to, my obligation neither to disclose nor to use Company Confidential Information other than for the Company's exclusive benefit and my obligations not to compete and not to solicit are necessary to protect Company Confidential Information and, consequently, to preserve the value and goodwill of the Company. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by the Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

7.2 In the event that a court finds this Agreement, or any of its restrictions, to be overbroad, ambiguous, unenforceable, or invalid, I and the Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

7.3 The covenants contained in Section 5 and 6 above shall be construed as a series of separate covenants, one for each city, county and state of any geographic area in the Restricted Territory. If the court declines to enforce this Agreement in the manner provided in subsection 7.2, the Company and I agree that this Agreement will be automatically modified to provide the Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

8. NO CONFLICTING AGREEMENT OR OBLIGATION. I represent that my performance of all the terms of this Agreement and as an employee of the Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by the Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement.

9. RETURN OF COMPANY PROPERTY. When I leave the employ of the Company, I will deliver to the Company any and all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information that I received in my role as an employee of the Company or Confidential Information of the Company. I agree that I will not copy, delete, or alter any non-personal information contained upon my Company computer or Company equipment before I return it to the Company. In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide the Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide the Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on the Company's premises and owned by the Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by the Company's personnel at any time with or without notice. Prior to leaving, I will cooperate with the Company in attending an exit interview and completing and signing the Company's termination statement if required to do so by the Company.

10. LEGAL AND EQUITABLE REMEDIES.

10.1 I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to the Company, and the Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach or threatened breach of this Agreement.

10.2 I agree that if the Company is successful in whole or in part in any material legal or equitable action under this Agreement (including, but not limited to, a court partially or fully granting any application, motion, or petition by the Company for injunctive relief, including, but not limited to, a temporary restraining order, preliminary injunction, or permanent injunction), whether against or commenced by me, the Company will be entitled to recover from me all costs, fees, or expenses it incurred at any time during the course of the dispute, including, but not limited to, reasonable attorney's fees. A final resolution of such dispute or a final judgment is required as a prerequisite to the Company's right to demand payment hereunder and such amounts must be paid by me to the Company within thirty (30) days after I receive written notice of such demand. In the event the Company demands only a portion of such costs, fees, or expenses incurred, such demand shall be without prejudice to further demands for (i) the remainder of any outstanding costs, fees, or expenses incurred, or (ii) costs, fees, or expenses incurred after the prior demand. Notwithstanding anything to the contrary in this provision, the Company shall pay any fees charged by an arbitral body (e.g., JAMS).

10.3 In the event the Company enforces this Agreement through a court order, I agree that the restrictions of Sections 5 and 6 will remain in effect for a period of twelve (12) months from the effective date of the Order enforcing the Agreement.

11. NOTICES. Any notices required or permitted under this Agreement will be given to the Company at its headquarters location at the time notice is given, labeled "Attention Chief Executive Officer," and to me at my address as listed on the Company payroll, or at such other address as the Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five (5) business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

12. PUBLICATION OF THIS AGREEMENT TO SUBSEQUENT EMPLOYER OR BUSINESS ASSOCIATES OF EMPLOYEE

12.1 If I am offered employment or the opportunity to enter into any business venture as owner, partner, consultant or other capacity while the restrictions described in Sections 5 and 6 of this Agreement are in effect, I agree to inform my potential employer, partner, co-owner and/or others involved in managing the business with which I have an opportunity to be associated of my obligations under this Agreement and also agree to provide such person or persons with a copy of this Agreement.

12.2 I agree to inform the Company of all employment and business ventures which I enter into while the restrictions described in Sections 5 and 6 of this Agreement are in effect and I also authorize the Company to provide copies of this Agreement to my employer, partner, co-owner and/or others involved in managing the business with which I am employed or associated and to make such persons aware of my obligations under this Agreement.

13. GENERAL PROVISIONS.

13.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of New Jersey as such laws are applied to agreements entered into and to be performed entirely within New Jersey between residents of New Jersey. I hereby expressly consent to the personal jurisdiction and venue of the state and federal courts located in the State of New Jersey for any lawsuit filed there against me by the Company arising from or related to this Agreement.

13.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

13.3 Successors and Assigns. This Agreement is for my benefit and the benefit of the Company, its successors, assigns, parent corporations, subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives. Notwithstanding anything to the contrary herein, the Company may assign this Agreement and its rights and obligations under this Agreement to any successor to all or substantially all of the Company's stock, whether by merger, consolidation, reorganization, reincorporation, sale of stock, or otherwise. For avoidance of doubt, the Company's successors and assigns are authorized to enforce the Company's rights under this Agreement.

13.4 Survival. This Agreement shall survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by the Company to any successor in interest or other assignee.

13.5 Employment At-Will. I agree and understand that nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by the Company, nor will it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause or advance notice.

13.6 Waiver. No waiver by the Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement will be construed as a waiver of any other right. The Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

13.7 Export. I agree not to export, reexport, or transfer, directly or indirectly, any U.S. technical data acquired from the Company or any products utilizing such data, in violation of the United States export laws or regulations.

13.8 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall be taken together and deemed to be one instrument. This Agreement may also be executed and delivered by facsimile signature, PDF or any electronic signature complying with the U.S. federal E-SIGN Act of 2000 (e.g., www.docusign.com).

13.9 Advice of Counsel. I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.

13.10 Entire Agreement. This Agreement, together with the Exhibits herein and any executed written offer letter between me and the Company, is the final, complete and exclusive agreement between me and the Company with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us; provided, however, prior to the execution of this Agreement, if the Company and I were parties to any agreement regarding the subject matter hereof, that agreement will be superseded by this Agreement prospectively only. No modification of or amendment to this Agreement will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

13.11 Protected Activity Not Prohibited. I understand that nothing in this Agreement limits or prohibits me from filing a charge or complaint with, or otherwise communicating or cooperating with or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"), including disclosing documents or other information as permitted by law, without giving notice to, or receiving authorization from, the Company, discussing the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act. Notwithstanding, in making any such disclosures or communications, I agree to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company Confidential Information to any parties other than the Government Agencies. I further understand that I am not permitted to disclose the Company's attorney-client privileged communications or attorney work product.

[signatures to follow on next page]

This Agreement will be effective as of my first day of service with the Company.

EMPLOYEE:

I HAVE READ THIS AGREEMENT CAREFULLY AND UNDERSTAND ITS TERMS. I HAVE COMPLETELY FILLED OUT EXHIBIT A TO THIS AGREEMENT.

/s/ Daniel Tasse

(Signature)

Daniel Tasse

Name

Nov 15, 2018

Date

Employee Confidential Information and Inventions Assignment Agreement
Signature Page

EXHIBIT A

PRIOR INVENTIONS

1. Except as listed in Section 2 below, the following is a complete list of all inventions or improvements relevant to the subject matter of my employment by DBV Technologies S. A., its subsidiaries, parents, affiliates, successors and assigns (together the "Company") that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements.

See below:

Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to inventions or improvements generally listed below, the intellectual property rights and duty of confidentiality with respect to which I owe to the following party(ies):

	Invention or Improvement	Party(ies)	Relationship
1.	<hr/>	<hr/>	<hr/>
2.	<hr/>	<hr/>	<hr/>
3.	<hr/>	<hr/>	<hr/>

Additional sheets attached.

Date:

Signature

Name of Employee (typed or printed)

EXHIBIT 3
(Section 9 of Executive Agreement)

- I. Companies with existing ownership interest -
 - BioQ Pharma. Private company, registered in California
 - Alcresta Therapeutics, LLC. Private company, registered in Delaware
 - Indivior PLC (INDV—London Stock Exchange)
 - Bellerophon Therapeutics, inc (Nasdaq — BLPH)
 - Pierian Biosciences. Private company, based in Nashville
- II. Company for which transition services will continue through March 31, 2019—
 - Alcresta Therapeutics, LLC. Private company, registered in Delaware
- III. Companies with Board position that will continue—
 - Indivior PLC (London Stock Exchange — INDV)
 - Regenzbio Inc. (Nasdaq — RGNX)
- IV. Companies with Board position that Executive will resign by June 30, 2019—
 - Bellerophon Therapeutics, Inc (Nasdaq – BLPH)
 - HLS Therapeutics, Inc (Toronto Stock Exchange — HLS.V)
 - BioQ Pharma. Private company, registered in California (resignation will occur prior to start date)

EXHIBIT 4
(Form of Release)

FORM OF RELEASE

This Release Agreement ("**Release**" or "**Agreement**") is made by and between **Daniel Tasse** ("you") and **DBV Technologies S.A.** (the "**Company**"). A copy of this Release is an attachment to the Executive Agreement between the Company and you dated [DATE] (the "**Executive Agreement**"). Capitalized terms not defined in this Agreement carry the definition found in the Executive Agreement.

1. Severance Benefits. In consideration for your execution, return and non-revocation of this Release on or after your Separation Date, the Company will provide you with the Severance Benefits described in Section 10(b) or (e) of the Executive Agreement.

2. Compliance with Section 409A. The Severance Benefits offered to you by the Company are payable in reliance on Treasury Regulation Section 1.409A-1(b)(9) and the short term deferral exemption in Treasury Regulation Section 1.409A-1(b)(4). For purposes of Code Section 409A, your right to receive any installment payments (whether pay in lieu of notice, Severance Benefits, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment shall at all times be considered a separate and distinct payment. All payments and benefits are subject to applicable withholdings and deductions.

3. Release. In exchange for the Severance Benefits and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "**Employee Parties**"), hereby generally and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "**Company Parties**") of and from any and all claims, liabilities, demands, contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to your employment with the Company or the termination of that employment (individually a "**Claim**" and collectively "**Claims**"). The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing in connection with your employment with the Company or the termination of that employment;
- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: the Age Discrimination in Employment Act, as amended ("**ADEA**"); Title VII of the Civil Rights Act of 1964, as amended; the Civil Rights Act of 1991; 42 U.S.C. § 1981, as amended; the Equal Pay Act; the Americans With Disabilities Act; the Genetic Information Nondiscrimination Act; the Family and Medical Leave Act; the New Jersey Law Against Discrimination; the New Jersey Conscientious Employee Protection Act; the New Jersey Law on Equal Pay; the New Jersey Political Activities of Employees Law; the New Jersey Genetic Testing Law; the New Jersey Family Leave Act; [the New York State Human Rights Law, the New York Equal Opportunity for Disabled Persons Act; the New York City Human Rights Law]¹; the Employee Retirement Income Security Act; the Employee Polygraph Protection Act; the Worker Adjustment and Retraining Notification Act; the Older Workers Benefit Protection Act; the Lilly Ledbetter Fair Pay Act; the Fair Credit Reporting Act; and the National Labor Relations Act;
- has violated any statute, public policy or common law (including but not limited to Claims for retaliatory discharge; negligent hiring, retention or supervision; defamation; intentional or negligent infliction of emotional distress and/or mental anguish; intentional interference with contract; negligence; detrimental reliance; loss of consortium to you or any member of your family and/or promissory estoppel) in connection with your employment with the Company or the termination of that employment.

¹ Only applicable if employment in NY.

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed and you are not releasing any right of indemnification you may have under your indemnification agreement or the Company's organizational documents or otherwise for any liabilities arising from your actions within the course and scope of your employment with the Company or within the course and scope of your role as a member of the Board of Directors and an officer of the Company. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. You also do not waive or release your rights or Claims to vested benefits under the written terms of the Company 401(k) plan, rights or Claims for unemployment compensation benefits, medical Claims incurred during your employment that is payable under applicable medical plans or an employer-insured liability plan, rights or Claims to any other Accrued Obligations (as defined in the Executive Agreement), rights or claims to vested equity rights relating to ordinary shares of the Company, rights or Claims to accrued benefits or any benefits to which you are entitled under this Agreement, or Claims relating to directors' and officers' liability insurance coverage. Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal government agency, or similar state or local agency ("**Government Agencies**"), or exercising any rights pursuant to Section 7 of the National Labor Relations Act. You further understand this Agreement does not limit your ability to voluntarily communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that you are otherwise waiving, to the fullest extent permitted by law, any and all rights you may have to individual relief based on any Claims that you have released and any rights you have waived by signing this Agreement. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company.

In addition, you will continue to be covered by the Company's indemnification protections following the end of your employment in accordance with Section ___ of the Company's bylaws which obligates the Company to indemnify and hold harmless employees, officers and directors, including former employees, officers and directors, from claims, losses, liabilities or damages imposed upon such individuals in connection with their employment with the Company or its subsidiaries. The Company's indemnification rights cover actions taken in the good faith belief that such action, strategy or course of conduct was in the best interests of the Company. Indemnification rights generally provides for advance reimbursement of reasonable attorney's fees and other defense related expenditures. Intentional violations of law or Company's policy are excluded from indemnification and expense reimbursement.

4. Your Acknowledgments and Affirmations. You also acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is in addition to anything of value to which you were already entitled, and (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim. You affirm that all of the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law. In addition, you acknowledge that you are knowingly and voluntarily waiving and releasing any rights you may have under the ADEA ("**ADEA Waiver**"). You also acknowledge that the consideration given for the ADEA Waiver is in addition to anything of

value to which you were already entitled. You further acknowledge that you have been advised by this writing, as required by the ADEA, that: (a) your release and waiver herein does not apply to any rights or claims that arise after the date you sign this Agreement; (b) you should consult with an attorney prior to signing this Agreement; (c) you have [twenty-one (21) {OR} forty-five (45)] days to consider this Agreement (although you may choose to voluntarily sign it sooner); (d) you have seven (7) days following the date you sign this Agreement to revoke it (by sending written revocation directly to [name/title]); (e) the Agreement will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth (8th) day after you sign this Agreement; and (f) if your employment is terminated as part of the group termination, you shall receive an attachment to this Agreement that identifies: (i) the decisional unit, which means the class, unit, or group of individuals covered by the offer of the payment(s) in consideration for signing this Agreement as a part of a group termination; (ii) the factors the Company used to determine who was eligible or selected for the employment termination program; (iii) the time limits for the employment termination program; (iv) the job titles and ages of all individuals within the decisional unit who were made eligible or selected; and (v) the job titles and ages of all individuals within the decisional unit who were not selected or made eligible.

5. Return of Company Property. By the Termination Date, you agree to return to the Company all Company documents (and all copies thereof) and other Company property that you have had in your possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Please coordinate return of Company property with [name/title]. **Receipt of the Severance Benefits described in Section 1 of this Agreement is expressly conditioned upon material compliance with this Section.**

6. Confidential Information and Post-Termination Obligations. Both during and after your employment you acknowledge your continuing obligations under your Employee Confidential Information and Inventions Assignment Agreement not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitations and competitive activities. Confidential information that is also a "trade secret," as defined by law, may be disclosed (A) if it is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, in the event that you file a lawsuit for retaliation by the Company for reporting a suspected violation of law, you may disclose the trade secret to your attorney and use the trade secret information in the court proceeding, if you: (A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order.

7. Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; *provided, however*, that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

8. Non-Disparagement. Both you and the Company agree not to disparage the other party, and the other party's officers, directors, employees, shareholders and agents, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that both you and the Company will respond accurately and fully to any question, inquiry or request for information when required by legal process. The Company's obligations under this Section are limited to Company representatives with knowledge of this provision. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

9. No Admission. This Agreement does not constitute an admission by you or the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

10. Breach. You agree that upon any material breach of this Agreement you will forfeit all amounts paid or owing to you under this Agreement. Further, you acknowledge that it may be impossible to assess the damages caused by your material violation of the terms of Sections 5, 6, 7, and 8 of this Agreement and further agree that any threatened or actual material violation or breach of those Sections of this Agreement will constitute immediate and irreparable injury to the Company. You therefore agree that in addition to any and all other damages and remedies available to the Company upon your material breach of this Agreement, the Company may seek an injunction to prevent you from violating or breaching this Agreement.

11. Miscellaneous. This Agreement constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of New Jersey as applied to contracts made and to be performed entirely within New Jersey.

DBV Technologies S.A.

By: _____

Name:

Title:

Daniel Tasse

EXHIBIT 5
(Indemnification Agreement)

INDEMNIFICATION AGREEMENT

WHEREAS

The public offering in the United States by DBV Technologies (the “Company”) of shares in the form of American Depositary Shares (“ADSs”), two ADSs representing one ordinary share of the Company, the filing of forms with the Securities and Exchange Commission (“SEC”) in connection with such public offering and the quotation of the ADSs on the Nasdaq Global Market (“Market”) expose the directors and the officers of the Company to major and specific risks with respect to their service to the Company.

The Company, taking into account the scope of the obligations and possible personal liability of the directors and officers induced by the U.S. securities laws and the fact that they are significantly more burdensome than under French law, has resolved that the said directors and officers should not be exposed to such personal liability.

Moreover, in the United States, directors and officers are typically indemnified or insured. As a result, the Company has concluded that in the absence of such protection against risks sustained by reason of the fact that they are serving as such, individuals might not accept to serve as directors or officers of the Company or might resign from their office. The Company has also concluded that it is necessary to have such individuals serve on its board of directors and as its officers if it is to achieve its objectives in the international financial and commercial markets.

It is the Company’s intention to provide said directors and officers with indemnification against liabilities and advancement of expenses in connection with any matters that arise out of their service to the Company to the fullest extent permitted by applicable laws and regulations.

Accordingly, considering as well the fact that the quotation of the ADSs on the Market is a key factor to the future development of the Company, the Company resolved that providing insurance coverage, indemnification and advancement of expenses to said directors and officers to the fullest extent permitted by applicable laws and regulations is consistent with the Company’s corporate interest.

NOW THEREFORE, THE COMPANY HEREBY IRREVOCABLY UNDERTAKES AS FOLLOWS:

1. Beneficiary

The persons, whether individuals or corporations, who may benefit from and accept the offer (the “**Offer**”) are:

(i) a director (a “**Director**”) of the Company, and

(ii) the Chairman of the Board, the *Directeur Général*, a *Directeur Général Délégué* as well as any executive officer, who is not a director, employed by the Company to whom the Board of Directors of the Company would elect to make the Offer (an “**Officer**”).

A “**Beneficiary**”, for the purpose of the Offer, shall be a Director or an Officer having accepted and signed this Offer.

2. Undertaking to Subscribe; Insurance Policy; Indemnification

2.1. Upon acceptance and signature of this Offer by a Beneficiary, the Company shall immediately provide to the Beneficiary the benefit of one or more director and officer (“**D&O**”) insurance policies (collectively, the “**D&O Insurance Policy**”) subscribed with a well-rated insurance company of national or international repute (the “**Insurance Company**”) providing D&O insurance coverage in line with best practice for companies in the United States with a similar market capitalization and industry to the Company (“**Best Practices**”), to the fullest extent permitted by applicable laws and regulations. Any losses incurred by the Beneficiary for any damages, losses, liabilities, judgments, fines, penalties (whether civil, criminal or other) and amounts paid in settlement (if such settlement is approved in advance by the Company, which approval shall not be unreasonably withheld), including without limitation all interest, assessments and other charges paid or payable in connection with or in respect of any of the foregoing (collectively, the “**Losses**”) if the Beneficiary is or was or becomes a party to or witness or other participant in, or is threatened to be made a party to or witness or other participant in, any threatened, pending or completed claim, demand, action, suit, proceeding or alternative dispute resolution mechanism, whether civil, criminal, administrative, investigative or other, whether formal or informal, or any inquiry or investigation, whether made, instituted or conducted by the Company or any other party, including without limitation any foreign, federal, state or other governmental entity by reason of (or arising in part out of) any event or occurrence related to the fact that the Beneficiary is or was a Director or Officer of the Company, or any Subsidiary of the Company (as defined below), or is or was serving at the request of the Company as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action or inaction on the part of the Beneficiary while serving in such capacity, shall be referred hereunder, collectively, as an “**Indemnifiable Claim**”. The Beneficiary shall be compensated for any Indemnifiable Claim by this D&O Insurance Policy or if not indemnifiable thereunder, by the Company to the fullest extent permitted by law. Also to the fullest extent permitted by applicable laws and regulations, the D&O Insurance Policy shall provide for indemnification of the Beneficiary in line with Best Practices against reasonable and necessary Expenses (as defined) as a result of the facts, acts or omission described above, in the event the Beneficiary was, is or is threatened to be made, a party or witness or participant in, by whatever means, a hearing or investigation which the Beneficiary in good faith and reasonably thinks could lead to an action or other relief, suit, proceeding or alternative dispute resolution mechanism, whether civil, criminal, administrative, or other, whether formal or informal. For purposes of this Agreement, a “**Subsidiary**” shall mean an entity, which the Company directly or indirectly controls, 50% or more of the entity’s voting securities.

For the purpose of the Offer, a “**Claim**” means (1) any threatened, asserted, pending or completed claim, demand, action, suit or proceeding, whether civil, criminal, administrative, arbitrative, investigative or other, and whether made pursuant to foreign federal, state or other law; and (2) any inquiry or investigation, whether made, instituted or conducted by the Company or any other party, including without limitation any foreign, federal, state or other governmental entity, that Beneficiary determines might lead to the institution of any such claim, demand, action, suit or proceeding.

To the fullest extent permitted by applicable laws and regulations, the D&O Insurance Policy shall provide for indemnification of the Beneficiary in line with Best Practices against reasonable and necessary expenses (including attorneys’ fees and all other costs, expenses and expenses incurred in connection with investigating, defending, being a witness in or participating in (including on appeal), or preparing to defend, be a witness in or participate in, any such action, suit, proceeding, alternative dispute resolution mechanism, hearing, inquiry or investigation) (collectively, hereinafter “**Expenses**”) and any and all Losses in connection with an Indemnifiable Claim.

The Company shall in the first instance pay on behalf of the Beneficiary any deductible or retention amounts due under the Insurance Policy in connection with any Indemnifiable Claim or Claim for the payment of Expenses, to the fullest extent permitted by applicable laws and regulations.

2.2. As a result of the acceptance and signature of this Offer by the Beneficiary, a bilateral contract will be formed between the Company and the Beneficiary.

2.3. To the fullest extent permitted by applicable laws and regulations, the Company agrees that, so long as a Director or Officer shall continue to serve as a Director or Officer of the Company or any Subsidiary, or shall continue at the request of the Company to serve as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, and thereafter so long as a Director or Officer shall be subject to any possible Indemnifiable Claim by reason of the fact that said Director or Officer was a Director or Officer of the Company or any Subsidiary or at the request of the Company to serve as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, and thereafter, the Company will maintain in effect for the benefit of such Director or Officer one or more valid, binding and enforceable insurance policies with the Insurance Company providing coverage, including with respect to limits of liability thereunder, at least comparable to that provided in this Offer, and such insurance policy or policies shall be or be deemed to be the D&O Insurance Policy for all purposes of this Offer.

3. Exclusions

The Beneficiary acknowledges that French law contains material limitations on indemnification or coverage for Losses and/or Expenses and currently prevents the Company, in particular, from indemnifying the Beneficiary for Losses and Expenses incurred by a Beneficiary with respect to the following Claims:

- (i) any Claim made by the Company or by a shareholder or any other person on behalf of the Company (derivative action);
- (ii) any Claim relating to remuneration paid to the Beneficiary, if it shall be determined that such remuneration was not due;

(iii) any Claim for which a judgment is rendered against the Beneficiary for an accounting of profits made from the purchase or sale of, or the procurement to purchase or sell, securities of the Company pursuant to insider trading laws or regulations;

(iv) any Claim which is based on the Beneficiary's willful or gross misconduct or on a fraud or a fraudulent misrepresentation, intentional or fraudulent (or deemed to be so) misconduct, whether the Beneficiary has acted alone or as an accomplice if it should be finally determined that the Beneficiary is guilty of such misconduct; or

(v) any Claim which is based on the Beneficiary's criminal actions.

The Beneficiary further acknowledges that the D&O Insurance Policy contains or may contain similar limitations on coverage for Losses or Expenses incurred by a Beneficiary, in each case with respect to Indemnifiable Claims, and that it does not cover Claims (i) pending, if any, at the date this Offer is accepted and signed by the relevant Beneficiary, (ii) which arise from the settlement of any action or Claim without the Company's written consent or, generally, that cannot be insured under applicable laws and regulations;

provided that the terms of the D&O Insurance Policy shall determine whether insurance coverage is available to the Beneficiary in connection with any Indemnifiable Claim, and that any limitations, restrictions or exclusions contained in the Insurance Policy that are not mandated by applicable law shall not relieve the Company of its obligation to provide indemnification to the Beneficiary for Losses and Expenses in each case with respect to Indemnifiable Claims to the fullest extent permitted by applicable laws and regulations.

4. Notification and Defense of an Indemnifiable Claim

4.1. As soon as practicable after the written receipt by the Beneficiary of a Indemnifiable Claim, the Beneficiary shall notify the Company in writing thereof, which notification shall specify:

- the existence and the nature of the Indemnifiable Claim; and
- the nature and the estimate of the amount of the Losses and Expenses with respect to an Indemnifiable Claim.

Omission so to notify the Company will not relieve the Company from liability under the Offer, except if thereby the Company has been materially prejudiced.

4.2. In the event the Company shall be requested by Beneficiary to pay the Expenses or Losses of any Indemnifiable Claim, the Company, if appropriate, shall be entitled to assume the defense of such Indemnifiable Claim, or to participate to the extent permissible in such Indemnifiable Claim, with counsel reasonably acceptable to Beneficiary. Upon assumption of the defense by the Company and the retention of such counsel by the Company, the Company shall not be liable to Beneficiary under this Agreement for any Expenses of counsel subsequently incurred by Beneficiary with respect to the same Indemnifiable Claim, provided that Beneficiary shall have the right to employ separate counsel in such Indemnifiable Claim at Beneficiary's sole cost and expense. Notwithstanding the foregoing, if Beneficiary's counsel delivers a written notice to the Company stating that such counsel has reasonably concluded that there may be a conflict of interest between the Company and Beneficiary in the conduct of any such defense or the Company shall not, in fact, have employed counsel or otherwise actively pursued the defense of such Indemnifiable Claim within a reasonable time, then in any such event the fees and expenses of Beneficiary's counsel to defend such Indemnifiable Claim shall be subject to the indemnification and advancement of Expenses provisions of this Agreement.

No settlement of any Claim shall be agreed upon and entered into without the Company's prior written consent, not to be unreasonably withheld. By default of such Company's prior written consent, the Company will be relieved from any and all liability for such settlement of a Indemnifiable Claim, if thereby the Beneficiary has been excluded from D&O Insurance Policy coverage or benefit and/or if thereby the Company has been materially prejudiced.

5. Advance on Reimbursement of Expenses

(a) To the fullest extent permitted by applicable laws and regulations and provided always that the Beneficiary has acted in good faith and within his or her capacities as a Director or Officer of the Company, the Expenses reasonably incurred by the Beneficiary in defending or investigating any Indemnifiable Claim duly notified to the Company shall be paid by the Insurance Company or by default if any payment demand to the Insurance Company remains unsatisfied after 30 days, as well as if the maximum insurance coverage under such D&O Policy is exceeded, by the Company, in advance of a final determination of the matter upon the request of the Beneficiary, upon presentation of satisfactory evidence that such Expenses have been incurred and remittance to the Insurance Company or, as the case may be, the Company of Beneficiary's written commitment to repay these Expenses in the event that it is ultimately determined that the Beneficiary is not entitled to have these Expenses reimbursed;

provided that the Company shall not be liable for that portion of such Expenses actually provided to the Beneficiary under the D&O Insurance Policy (to the fullest extent permitted by applicable laws and regulations, such undertaking shall be accepted without reference to the financial ability of the Beneficiary to make repayment and any advances and undertakings to repay pursuant to this Section 5 shall be unsecured and interest-free); and provided further that no indemnification shall be permitted (A) in the event that is finally determined that : (i) the Beneficiary's conduct forming the subject matter of the Indemnifiable Claim was not consistent with the corporate interests of the Company; (ii) the Beneficiary's conduct was in bad faith, knowingly fraudulent or deliberately dishonest or constituted willful misconduct or (B) in respect of Indemnifiable Claims initiated or brought by Beneficiary against the Company or its directors, officers, employees or other agents and not by way of defense, except with respect to proceedings brought to establish or enforce a right to indemnification under this Agreement or otherwise available to Beneficiary under another agreement or applicable law.

(b) The termination of any Claim pursuant to a Indemnifiable Claim by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, absent specific findings in respect of Beneficiary in the judgement, conviction of the Beneficiary or an acknowledgment by the Beneficiary in the settlement itself, create a presumption that the Beneficiary did not act in good faith and in a manner that the Beneficiary reasonably believed to be in, or not opposed to, the best interests of the Company, and, with respect to any criminal proceeding, had reasonable cause to believe that his or her conduct was unlawful.

(c) The Beneficiary shall cooperate with the person, persons or entity making such determination with respect to the Beneficiary's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to the Beneficiary and reasonably necessary to such determination.

(d) **Partial Indemnification.** If the Beneficiary is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of the Expenses and Losses, in each case with respect to an Indemnifiable Claim, paid in settlement actually and reasonably incurred by or on behalf of the Beneficiary in connection with any Claim but not, however, for the total amount thereof, the Company shall nevertheless indemnify the Beneficiary for the portion of such Expenses or Losses, in each case with respect to an Indemnifiable Claim, to which the Beneficiary is entitled.

6. Payment by Company

To the fullest extent permitted by applicable laws and regulations and provided always that the Beneficiary has acted in good faith and within his or her capacities as a Director or Officer of the Company, in the event that a Beneficiary shall not be indemnified for all the Expenses and Losses, in each case with respect to an Indemnifiable Claim, due to (a) the failure of the Company to obtain or maintain the D&O Insurance Policy in accordance with this Offer, as well as if the maximum insurance coverage shall be exceeded or (b) the failure of the D&O Insurance Policy to pay the Expenses or Losses, in each case with respect to an Indemnifiable Claim, the Company shall pay in full to the Beneficiary the amount of any such Expenses and Losses, in each case with respect to an Indemnifiable Claim, to which the Beneficiary is entitled to be reimbursed or shall pay the difference between the amount received by the Beneficiary from the Insurance Company and such amount of reimbursement of the Expenses and Losses, in each case with respect to an Indemnifiable Claim, to which it is so entitled, as the case may be.

7. Subrogation; Primacy of Indemnification

Except as provided for below, in the event of payment by the Company to Beneficiary under the Offer, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Beneficiary, who shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the Company effectively to bring suit to enforce such rights.

8. Right to Payment Upon Application

Subject to the terms and conditions of Section 5 hereof, all payment under the Offer, including relating to the reimbursement of the Expenses or any advances of Expenses or payment of Losses, in each case with respect to an Indemnifiable Claim, shall be paid by the Company, or on its behalf, within 30 days after a written Claim for payment has been received by the Company. Expenses reasonably incurred by the Beneficiary in connection with successfully establishing the right to payment according to the Offer, in whole or in part, shall also be paid by the Company, to the fullest extent permitted by applicable laws and regulations.

9. Offer Not Exclusive

This Offer shall not be deemed exclusive of any other rights to which the Beneficiary may be entitled under any agreement, any vote of shareholders or disinterested directors, statute, or otherwise.

10. Notices

10.1. Any notices served pursuant to this Offer shall be sent by registered mail with return receipt requested or delivered by hand against receipt if to the Company to the registered office, if to the Beneficiary to the address indicated below at the end of this Offer.

10.2. Any change of address shall be notified by the relevant party to the other party by registered mail with return receipt requested or delivered by hand against receipt within fifteen (15) days of the actual date of change of address.

10.3. Notices shall be deemed to have been received on the date of reception of the registered letter, as evidenced by the return receipt or, as the case may be, of the letter delivered by hand, as evidenced by the receipt.

11. Amendments- Assignment

11.1. No alteration of, amendment to or waiver of any of the provisions of this Offer shall be binding on any of the parties unless it is written and executed by a duly authorized representative of each of the parties.

11.2. This Offer may not be assigned by any party hereto except with the prior written consent of the other party. Without limiting the generality or effect of the foregoing, the Beneficiary's right to receive payments hereunder shall not be assignable, whether by pledge, creation of a security interest or otherwise, other than by a transfer by the Beneficiary's will or by the laws of descent and distribution, and, in the event of any attempted assignment or transfer contrary to this Section 11.2, the Company shall have no liability to pay any amount so attempted to be assigned or transferred.

12. Successors

The legal representatives of the parties or their successors shall be bound by and may rely on all the terms of the Offer. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation, reorganization or otherwise) to all or substantially all of the business or assets of the Company, by agreement in form and substance satisfactory to the Beneficiary and his or her counsel, expressly to assume and agree to perform this Agreement in the same manner and to the same extent the Company would be required to perform if no such succession had taken place. This Agreement shall be binding upon and inure to the benefit of the Company and any successor to the Company, including without limitation any person acquiring directly or indirectly all or substantially all of the business or assets of the Company whether by purchase, merger, consolidation, reorganization or otherwise (and such successor will thereafter be deemed the "Company" for purposes of this Agreement), but shall not otherwise be assignable or delegatable by the Company. This Agreement shall inure to the benefit of and be enforceable by the Beneficiary's personal or legal representatives, executors, administrators, heirs, distributees, legatees and other successors.

13. Miscellaneous Provisions

13.1. Term of Agreement. This Agreement shall continue until and terminate upon the later of (a) ten years after the date that the Beneficiary shall have ceased to serve as a Director or Officer of the Company or a Subsidiary or, at the request of the Company, as a director, officer, partner, trustee, member, employee or agent of another corporation, partnership, joint venture, trust, limited liability company or other enterprise or (b) the final termination of all Claims pending on the date set forth in clause (a) in respect of which the Beneficiary is granted rights of indemnification or advancement of Expenses hereunder and of any Claim commenced by the Beneficiary pursuant to Section 8 of this Agreement relating thereto.

13.2. The parties agree that the provisions contained in the preamble and Exhibit hereto form an integral part of the Offer.

13.3. Should any of the provisions of this Offer be held null and void or unenforceable for any reason whatsoever, the parties undertake to use their best efforts to remedy the causes of such nullity, so that, except where such is impossible, the Offer shall remain in force without any discontinuity.

13.4. The parties agree to provide any information as well as to execute and to deliver all documents reasonably required for the performance of this Offer.

14. Applicable Law

This Offer shall be governed as to its validity, construction and performance in accordance with the laws of the Republic of France.

15. Disputes

Any dispute arising from the Offer or which are a result or a consequence thereof shall be made subject to the jurisdiction of the *Tribunal de Commerce de Paris*.

Executed in _____

On November 15, 2018

In two (2) original copies

By: /s/ David Schilansky

Name: David Schilansky

Title: Deputy Chief Executive Officer and Chief Financial Officer (*Directeur Financier*)

Accepted by /s/ Daniel Tassé
Daniel Tassé
Residing at _____
On November 15, 2018

being a Director or an Officer of the Company, as these terms are defined in the Offer

who hereby declares that he or she:

- has a good and fair knowledge of the terms, conditions and exclusions of the Offer;
- is fully aware that applicable French laws and regulations limit a company's ability to indemnify its directors against liability;
- is fully aware that U.S. securities laws may also limit a company's ability to indemnify in respect of liabilities arising under U.S. securities laws; and
- formally and irrevocably accepts the Offer, as it stands.

**FIRST AMENDMENT TO THE
EXECUTIVE AGREEMENT OF DANIEL TASSE**

This **FIRST AMENDMENT TO THE EXECUTIVE AGREEMENT OF DANIEL TASSE** the "**Amendment**") is entered into this 27th day of June 2019 (the "**Effective Date**"), by and between **DANIEL TASSE** (the "**Executive**") and **DBV TECHNOLOGIES S.A.** (the "**Company**").

RECITALS

A. The Company and the Executive have entered into that certain Executive Agreement effective November 29, 2018 (the "**Executive Agreement**"); and

B. In light of the Board's recent approval of the performance conditions applicable to severance payments under Section 10 of the Executive Agreement, the Company and the Executive desire to amend the Executive Agreement as provided in this Amendment.

AGREEMENT

The parties agree to the following:

1. **Amendment to Section 10(a)**. Section 10(a) of the Executive Agreement is hereby and replaced in its **entirety** as follows:

(a) **Performance Conditions**. In addition to the above requirements regarding shareholder approval, all severance payments under this Section are contingent upon and subject to the achievement of all of the following performance conditions:

(i) Approval of Viaskin® Peanut in a major market;

(ii) The Company's build of an EPIT® pipeline with three ongoing clinical trials; and

(iii) The existence of six months of cash runway as determined in accordance with the Company's spend in the calendar quarter preceding the date of severance.

2. **No Other Amendments**. Except as modified or amended in this Amendment, no other term or provision of the Executive Agreement is amended or modified in any respect. The Executive Agreement, and its exhibits, along with this Amendment, set forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by the Executive and an authorized officer of the Company.

The parties have executed this First Amendment to the Executive Agreement of Daniel Tassé on the day and year first written above.

DBV Technologies S.A.

/s/ David Schilansky

David Schilansky

Deputy CEO

EXECUTIVE:

/s/ Daniel Tasse

Daniel Tasse

EXECUTIVE AGREEMENT

This EXECUTIVE AGREEMENT (the “*Agreement*”) between DBV Technologies, Inc. (the “*Company*”), and Pharis Mohideen (the “*Executive*”) is effective on July 22, 2019 (the “*Effective Date*”).

WITNESSETH:

WHEREAS, the Company desires the Executive to provide services to the Company, and wishes to provide the Executive with certain compensation and benefits in return for such services; and

WHEREAS, the Executive wishes to be employed by the Company and to provide services to the Company in return for certain compensation and benefits;

NOW THEREFORE, in consideration of the foregoing, of the mutual promises contained herein and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **AT WILL EMPLOYMENT.** The Executive shall be employed at will, meaning that either the Company or the Executive may terminate this Agreement and the Executive’s employment at any time, for any reason or no reason, with or without Cause, subject to the terms and conditions of this Agreement. Any contrary representations that may have been made to the Executive shall be superseded by this Agreement. This Agreement shall constitute the full and complete agreement between the Executive and the Company on the “at-will” nature of the Executive’s employment with the Company, which may be changed only in an express written agreement signed by the Executive and a duly authorized officer of the Company. The Executive’s rights to any compensation following a termination shall be only as set forth in Section 10.

2. **POSITION & DUTIES.** The Executive shall serve as the Company’s Chief Medical Officer. The Executive shall have such other duties, authorities and responsibilities commensurate with the duties, authorities and responsibilities of persons in similar capacities in similarly sized companies and such other duties and responsibilities as the CEO shall designate that are consistent with the Executive’s position. The Executive shall use Executive’s best efforts to perform faithfully and efficiently the duties and responsibilities assigned to the Executive hereunder and devote all of the Executive’s business time (excluding periods of vacation and other approved leaves of absence) to the performance of the Executive’s duties with the Company.

3. **LOCATION.** Unless the parties otherwise agree in writing, at all times during Executive’s employment with the Company, the Executive shall perform services in accordance with the Company’s business needs and the permanent establishment guidelines between the Company’s offices in New York, New York, Summit, New Jersey and the Company’s offices in Montrouge and Bagneux, France *provided, however,* that the Company may from time to time require the Executive to travel temporarily to other locations (domestic and international) in connection with the Company’s business.

4. **BASE SALARY.** The Company agrees to pay the Executive a base salary (the “*Base Salary*”) at an annual rate of \$440,000 (USD), payable in accordance with the regular payroll practices of the Company. The Executive’s Base Salary shall be subject to review and adjustment from time to time by the Company in its sole discretion. Additionally, you will receive two (2) sign-on bonuses: 1) one in the amount of \$235,000 and 2) one in the amount of \$51,348 to be paid in the first full payroll period corresponding to your hire date. Should you voluntarily leave the Company within one year of these bonuses being paid, you will be required to repay both bonus amounts (\$286,348).

5. **ANNUAL BONUS.** With respect to each full calendar year during Executive’s employment with the Company (beginning in the year of the Effective Date), the Executive will be eligible to earn an annual performance bonus with a target amount of not less than forty percent (40%) of the Base Salary (the “*Annual Bonus*”). The Annual Bonus will be based upon the Company’s assessment of the Executive’s performance and the Company’s attainment of targeted goals as set by the Board in its sole discretion. The Annual Bonus, if any, will be subject to applicable payroll deductions and withholdings. Following the close of each calendar year, the Board will determine whether the Executive has earned the Annual Bonus, and the amount of any Annual Bonus (which, for clarity, actual performance may result in an Annual Bonus that becomes payable which is greater or less than such target amount noted above), based on the set criteria. No amount of the Annual Bonus is guaranteed, and, except as otherwise provided in this Agreement, the Executive must be employed in good standing on the last day of the annual performance period for the Annual Bonus to be eligible to receive an Annual Bonus for the calendar year. Executive shall be eligible to receive a pro-rated Annual Bonus for 2019. The Annual Bonus, if earned, will be paid no later than March 15 of the calendar year after the year in which it is earned. Your eligibility for an annual bonus is subject to change in the discretion of the Company. The amount of your bonus will be determined on the same basis as bonuses for other members of the company’s executive team

6. **EQUITY AWARDS.** The Executive shall be eligible to participate in the Company’s equity compensation program. Subject to Board approval, the Executive will initially be granted an option to purchase up to 75,000 ordinary shares of the Company as traded on the Euronext Paris Exchange with an exercise price equal to closing price of the share on the Euronext Paris Exchange on the day that the grant is recorded, but will not be less than the average of the share prices quoted over the twenty (20) trading days preceding the date of said grant (the date such options are granted the “Grant Date”). The options will vest over four (4) years with 25% of the shares subject to the option vesting on the one year anniversary of the Vesting Start Date and the remaining 75% of the shares subject to the option shall vest in six substantially equal bi-annual installments following the first anniversary of the Grant Date vesting in equal half-year installments over the following thirty-six (36) months, subject to the Executive’s continued employment with the Company through the applicable vesting dates. Additionally, Executive shall only be eligible to exercise the vested options granted pursuant to this Section 6 if (a) the Executive remains employed with the Company through the exercise date (subject to exceptions for Executive’s death or Disability under French law; and further subject to the provisions of the DBV Technologies S.A. Nonqualified Stock Option Plan and Grant Notice (the “*Option Agreement*”)) and (b) the Company has obtained the marketing approval from the U.S. Food and Drug Administration of Viaskin Peanut prior to the exercise date. The option award described above will be governed by and subject to the terms and conditions of any associated stock option agreement required to be entered into by Executive and the Company, including but not limited to **Exhibit 1**.

7. BENEFITS.

(a) **BENEFIT PLANS.** The Executive shall, in accordance with Company policy and the terms of the applicable Company benefit plan documents, be eligible to participate in any benefit plan or arrangement, including health, life and disability insurance, retirement plans and the like, that may be in effect from time to time and made available to the Company's senior management. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

(b) **VACATION.** The Executive shall be eligible to accrue vacation time at the rate of twenty (20) days per year in accordance with the Company's vacation policy. Vacation is to be taken at such intervals as shall be appropriate and consistent with the proper performance of the Executive's duties hereunder.

8. CONFIDENTIALITY AND POST-EMPLOYMENT OBLIGATIONS. As a condition of employment, the Executive agrees to execute and abide by the Company's current form of Employee Confidential Information and Invention Assignment Agreement ("***Confidentiality Agreement***"), which is attached hereto as **Exhibit 2** and which may be amended by the parties from time to time without regard to this Agreement by mutual consent between Executive and the Company. The Confidentiality Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

9. OUTSIDE ACTIVITIES DURING EMPLOYMENT. The Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business or prospects, financial or otherwise during Executive's employment with the Company without the written consent of the Board; provided, however, that this limitation shall not apply to any equity interest that Executive has in a Company which stock is publicly traded so long as Executive does not own more than 5% of such equity Except with the prior written consent of the Board, during Executive's employment with the Company the Executive will not undertake or engage in any other employment, occupation or business enterprise, except for passive investments. Notwithstanding the foregoing, nothing shall prevent the Executive from participating in charitable, civic, educational, professional, community or industry affairs or, with prior written approval of the Board. *Provided that* all such permitted activities or services in this Section 9 do not (i) create a conflict with Executive's employment hereunder; (ii) materially interfere with the performance of Executive's duties; or (iii) violate the terms of the Confidentiality Agreement.

10. TERMINATION OF EMPLOYMENT. The parties acknowledge that Executive's employment relationship with the Company is at-will. Either Executive or the Company may terminate the employment relationship at any time, with or without Cause.

(a) **Termination by the Company without Cause or for Good Reason.**

(i) The Company shall have the right to terminate Executive's employment with the Company pursuant to this Section 10(a) at any time, in accordance with Section 10(g), or without "Cause" (as defined in Section 10(b)(ii) below) by giving notice as described in Section 10(f) of this Agreement. A termination pursuant to Sections 10(e) below is not a termination without Cause for purposes of receiving the benefits described in this Section.

(ii) If the Company terminates Executive's employment at any time without Cause or Executive terminates Executive's employment with the Company for "Good Reason" (as defined in Section 10(a)(vii) below) and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "**Separation from Service**"), then Executive shall be entitled to receive the Accrued Obligations (defined in Section 10(a)(iv) below). If Executive complies with the obligations in Section 10(a)(iii) below, Executive shall also be eligible to receive the following "**Severance Benefits.**"

A. The Company will pay Executive an amount equal to the Executive's then current Base Salary for twelve (12) months (the "**Severance Period**"), less all applicable withholdings and deductions ("**Severance**"), paid in substantially equal installments over the Severance Period, with the first payment paid within sixty (60) days following the date of Executive's Separation from Service (the "**Separation Date**") and include an amount for the period from Executive's Separation Date and the first payment date and the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter for the duration of the Severance Period.

B. If Executive timely elects continued coverage under COBRA for Executive and Executive's covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Executive's and Executive's covered dependents' health insurance coverage in effect for himself (and Executive's covered dependents) on the Separation Date until the earliest of: (x) twelve (12) months following the Separation Date (the "**COBRA Severance Period**"); (y) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (z) the date Executive ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the Separation Date through the earlier of (x)-(z), (the "**COBRA Payment Period**"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Executive's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding (such amount, the "**Special Severance Payment**"), for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of Executive's rights under COBRA or ERISA for benefits under plans and policies arising under Executive's employment by the Company.

(iii) Executive will be paid all of the Accrued Obligations on the Company's first payroll date after Executive's date of termination from employment or earlier if required by law. Executive shall receive the Severance Benefits pursuant to Section 10(a)(ii) of this Agreement if: (v) within sixty (60) days following the date of Executive's Separation from Service, Executive has signed and delivered to the Company a separation agreement containing an effective, general release of claims in favor of the Company and its affiliates and representatives, in a form presented by and acceptable to the Company (the "**Release**"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "**Release Effective Date**"); (w) if Executive holds any other positions with the Company, including a position on the Board, Executive resigns such position(s) to be effective no later than the date of Executive's Separation Date (or such other date as requested by the Board); (x) Executive returns all Company property; (y) Executive complies with Executive's post-termination obligations under this Agreement and the Confidential Information Agreement; and (z) Executive complies with the terms of the Release, including without limitation any non-disparagement and confidentiality provisions contained in the Release. To the extent that any of the Severance Benefits are deferred compensation under Section 409A of the Code payable within the sixty (60) day period following the Executive's Separation Date, and are not otherwise exempt from the application of Section 409A, then, if the sixty (60) day period during which Executive may consider and sign the Release spans two calendar years, the payment of the Severance Benefits will not be made or begin until the later calendar year.

(iv) For purposes of this Agreement, "**Accrued Obligations**" are (w) any unpaid Base Salary through the date of termination and any accrued vacation; (x) any unpaid earned bonus earned with respect to any calendar year ending on or preceding the date of termination; (y) reimbursement for any approved unreimbursed expenses, incurred through the date of termination; and (z) all other payments and benefits to which the Executive may be entitled under applicable law, the terms of any applicable compensation arrangement or benefit, equity or perquisite plan or program or grant or this Agreement, including but not limited to any applicable insurance benefits and accrued and vested benefits under any retirement plan or nonqualified deferred compensation plan.

(v) The Severance Benefits provided to Executive pursuant to this Section 10(a) are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Company severance plan, policy or program.

(vi) Any damages caused by the termination of Executive's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Executive is eligible pursuant to Section 10(a)(ii) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

(vii) For purposes of this Agreement, "**Good Reason**" shall mean the occurrence of any of the following events without Executive's written consent: (i) a requirement that Executive relocate Executive's principal place of employment to a location more than fifty (50) miles from Summit, New Jersey or (ii) a material breach of this Agreement by the Company; *provided, however*, that, any such termination by Executive shall only be deemed for Good Reason pursuant to this definition if: (1) Executive gives the Company written notice of Executive's intent to terminate for Good Reason within ninety (90) days following the first occurrence of the condition(s) that Executive believes constitute(s) Good Reason, which notice shall describe such condition(s); (2) the Company fails to remedy such condition(s) within thirty (30) days following

receipt of the written notice (the “*Cure Period*”); (3) the Company has not, prior to receiving such notice from Executive, already informed Executive that Executive’s employment with the Company is being terminated and (4) Executive voluntarily terminates Executive’s employment within thirty (30) days following the end of the Cure Period.

(b) Termination by the Company for Cause.

(i) Subject to Section 10(c)(ii) below, the Company shall have the right to terminate Executive’s employment with the Company at any time for Cause by giving notice as described in Section 10(g) of this Agreement.

(ii) For purposes of this Agreement, “*Cause*” means first, the Executive’s conviction of any felony or any crime involving fraud or embezzlement under the laws of the United States or any state which conviction results in material harm to the reputation of the Company (which, for purpose of clarity, would exclude traffic offenses). Second, “*Cause*” means, as reasonably determined by the Chief Executive Officer, Executive’s acts or omissions that constitute the following conduct: (w) fraud or gross negligence against the Company causing material injury to the Company; (x) the material violation of any material Company policy (including but not limited to its sexual harassment policy) or any statutory duty owed to the Company which, in either case, results in material harm to the Company after Executive is provided with a reasonable opportunity of not less than fifteen (15) days to cure, to the extent curable, from the date written notice thereof is given to Executive by the Company; (y) unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (z) refusal to comply with a lawful directive of the Chief Executive Officer consistent with Executive’s position with the Company after Executive is provided with a reasonable opportunity of not less than fifteen (15) days to cure from the date notice thereof is given to Executive by the Company.

(iii) In the event Executive’s employment is terminated at any time for Cause, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, consistent with the Company’s standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

(c) Resignation by the Executive.

(i) Executive may resign from Executive’s employment with the Company at any time by giving notice as described in Section 10(f).

(ii) In the event Executive resigns from Executive’s employment with the Company other than for Good Reason, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company’s standard payroll policies, the Company shall provide to Executive the Accrued Obligations.

(d) Termination Without Cause or for Good Reason In Connection with a Change in Control.

(i) If Executive's employment by the Company is terminated by the Company (or its successor or parent) without Cause (and not due to Disability or death) or by Executive for Good Reason, in either case, within three (3) months before or on, or within twelve (12) months immediately following, a Change in Control (as defined in the Option Agreement), that constitutes a change in control event described in Treasury Regulation Sections 1.409A-3(i)(5), then: the Company shall pay or provide Executive with a lump sum equal to the target Annual Bonus, less applicable payroll deductions and withholdings, plus the same Severance Benefits described in Section 10(a)(ii), except that the amount payable in Section 10(a)(ii)(A) shall be paid to Executive in a lump sum within sixty (60) days following Executive's Separation Date, unless Executive's employment is terminated within three (3) months before the Change in Control in which case the severance shall be paid in installments as provided in Section 10(a)(ii)(A), and any remaining amount shall be converted into, and paid in, a lump sum on the date of the Change in Control, *provided that* Executive executes and does not revoke the Release and otherwise complies with the requirements of Section 10(a)(iii).

(e) Termination by Virtue of Death or Disability of the Executive.

(i) In the event of Executive's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll practices, provide to the Executive's legal representatives Executive's Accrued Obligations, including any life insurance benefits payable to Executive's beneficiary under the Company's group life insurance plan.

(ii) Subject to applicable law, the Company shall at all times have the right, upon written notice to Executive, to terminate this Agreement based on Executive's Disability (as defined below). Termination by the Company of Executive's employment based on "**Disability**" shall mean termination because the Executive has been unable due to a physical or mental condition to perform the essential functions of Executive's position with or without reasonable accommodation for a period of six (6) consecutive months and following the end of such six (6) month period the Executive has been determined to be disabled under the Company's long-term disability benefit plan and is eligible to receive benefits under such plan. In the event Executive's employment is terminated based on the Executive's Disability after the end of such six (6) month period, Executive will not receive the Severance Benefits, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall provide to Executive the Accrued Obligations and amounts owed to Executive under the Company's long-term disability plan.

(f) Effective Date of Termination.

(i) Termination of Executive's employment pursuant to this Agreement shall be effective on the earliest of:

A. thirty (30) days after the Company gives notice to Executive of Executive's termination with Cause, unless pursuant to Sections 10(b)(ii)(x) or 10(b)(ii)(z) in which case fifteen (15) days after notice if not cured or unless the Company specifies a later date, in which case, termination shall be effective as of such later date if not cured;

B. immediately upon the Executive's death;

C. thirty (30) days after the Company gives notice to Executive of Executive's termination on account of Executive's Disability, unless the Company specifies a later date, in which case, termination shall be effective as of such later date, *provided* that Executive has not returned to the full time performance of Executive's duties prior to such date;

D. thirty (30) days after the Executive gives written notice to the Company of Executive's resignation, *provided* that the Company may set a termination date at any time between the date of notice and the date of resignation, in which case the Executive's resignation shall be effective as of such other date. Executive will receive compensation through any required notice period;

E. for a termination for Good Reason, immediately after Executive's full satisfaction of the requirements of Section 10(a)(vii); or

F. thirty (30) days after the Company gives notice to Executive of Executive's termination without Cause.

G. In the event notice of a termination under subsections (i)(A), (C) and (F) is given orally, at the other party's request, the party giving notice must provide written confirmation of such notice within five (5) business days of the request in compliance with the requirements of Section 13 below. In the event of a termination for Cause, written confirmation shall specify the subsection(s) of the definition of Cause relied on to support the decision to terminate.

(g) **Effect of Termination.** Executive agrees that should the Executive's employment be terminated for any reason, Executive shall be deemed to have resigned from any and all positions with the Company and its subsidiaries, including any position on the Board.

(h) **Cooperation With Company After Termination of Employment.** For the period that you are receiving any Severance under this Agreement, Executive shall fully cooperate with the Company in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company; provided, that the Company shall reimburse Executive for any reasonable expenses incurred relating to such cooperation and such cooperation does not interfere with any subsequent employment of Executive by another employer.

11. **INDEMNIFICATION.** While serving as an executive of the Company and following termination of Executive's employment, Executive shall be covered by the Company's Directors and Officers Liability Insurance at levels no less favorable than existing directors and officers

12. **ASSIGNMENT.** This Agreement shall be binding upon and inure to the benefit of the Executive and the Executive's heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of the Executive's duties under this Agreement, neither this Agreement nor any rights or obligations under this Agreement shall be assignable by the Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives. Any

such successor or assign of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all, or substantially all, of the outstanding shares of the Company.

13. **NOTICE.** For the purpose of this Agreement, notices and all other communications provided for in this Agreement shall be in writing and shall be deemed to have been duly given (a) on the date of delivery if delivered by hand, (b) on the date of transmission, if delivered by e-mail, (c) on the first business day following the date of deposit if delivered by guaranteed overnight delivery service, or (d) on the fourth business day following the date delivered or mailed by United States registered or certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Company:

Joan Schmidt
General Counsel
DBV Technologies S. A.
25 DeForest Avenue, Suite 203
Summit, NJ 07901
joan.schmidt@dbv-technologies.com

and a copy (which shall not constitute notice) shall also be sent to:

Marc Recht
Cooley LLP
500 Boylston St.
Boston, MA 02116
mrecht@cooley.com

If to the Executive:

To the most recent address of the Executive set forth in the personnel records of the Company, or to such other address as either party may have furnished to the other in writing in accordance herewith, except that notices of change of address shall be effective only upon receipt.

14. **SECTION HEADINGS; INCONSISTENCY.** The section headings used in this Agreement are included solely for convenience and shall not affect, or be used in connection with, the interpretation of this Agreement. If there is any inconsistency between this Agreement and any other agreement (including but not limited to any option, stock, long-term incentive or other equity award agreement), plan, program, policy or practice (collectively, "**Other Provision**") of the Company the terms of this Agreement shall control over such Other Provision.

15. **SEVERABILITY.** The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof.

16. **COUNTERPARTS.** This Agreement may be executed in counterparts, each of which shall be deemed to be an original but all of which together will constitute one and the same instruments. One or more counterparts of this Agreement may be delivered by facsimile, with the intention that delivery by such means shall have the same effect as delivery of an original counterpart thereof.

17. **SECTION 409A.** It is intended that all of the severance benefits and other payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended (the "**Code**") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9), and this Agreement will be construed to the greatest extent possible as consistent with those provisions, and to the extent not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A. For purposes of Code Section 409A (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), Executive's right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by the Company at the time of Executive's separation from service (determined in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h) to be a "specified employee" for purposes of Code Section 409A(a)(2)(B)(i), and if any of the payments upon separation from service set forth herein and/or under any other agreement with the Company are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments as required in order to avoid a prohibited distribution under Code Section 409A(a)(2)(B)(i) and the related adverse taxation under Section 409A, such payments shall not be provided to Executive prior to the earliest of (i) the expiration of the six-month period measured from the date of Executive's separation from service with the Company, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit. Each installment of severance benefits is a separate "payment" for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). The Company makes no representations or warranties as to whether any payments under this Agreement are subject to Section 409A of the Code or exempt.

18. **ADDITIONAL LIMITATION.**

(a) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the “**Aggregate Payments**”), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be \$1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. § 1.280G-1, Q&A-24(b) or (c).

(b) For purposes of this Section 18, the “**After Tax Amount**” means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive’s receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes

(c) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 18(a) shall be made by a nationally recognized accounting firm selected by the Company, and reasonably acceptable to the Executive (the “**Accounting Firm**”), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days prior to the date of the consummation of the transaction or at such earlier time as is reasonably requested by the Company or the Executive. All costs of the Accounting Firm shall be borne by the Company.

19. **REPRESENTATIONS.** The Executive represents and warrants to the Company that the Executive has the legal right to enter into this Agreement and to perform all of the obligations on the Executive’s part to be performed hereunder in accordance with its terms and that the Executive is not a party to any agreement or understanding, written or oral, which could prevent the Executive from entering into this Agreement or performing all of the Executive’s obligations hereunder. The Executive further represents and warrants that Executive has been advised to consult with an attorney, and that Executive has carefully read and fully understand all of the provisions of this Agreement and that Executive is voluntarily entering into this Agreement.

20. **WITHHOLDING.** The Company may withhold from any and all amounts payable under this Agreement such federal, state and local taxes as may be required to be withheld pursuant to any applicable law or regulation.

21. **SURVIVAL.** The respective obligations of, and benefits afforded to, the Company and the Executive which by their express terms or clear intent survive termination of the Executive's employment with the Company, including, without limitation, the provisions of Sections 8 and 10-268, inclusive, of this Agreement, will survive termination of the Executive's employment with the Company, and will remain in full force and effect according to their terms.

22. **AGREEMENT OF THE PARTIES.** The language used in this Agreement will be deemed to be the language chosen by the parties hereto to express their mutual intent, and no rule of strict construction will be applied against any party hereto. No agreements or representations, oral or otherwise, express or implied, with respect to the subject matter hereof have been made by either party which are not expressly set forth in this Agreement. Neither the Executive nor the Company shall be entitled to any presumption in connection with any determination made hereunder in connection with any arbitration, judicial or administrative proceeding relating to or arising under this Agreement.

23. **INTEGRATION.** This Agreement, including the Confidentiality Agreement, contains the complete, final and exclusive agreement of the parties relating to the terms and conditions of the Executive's employment and the termination of the Executive's employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the parties.

24. **AMENDMENT.** This Agreement cannot be amended or modified except by a written agreement signed by the Executive and a duly authorized officer of the Company.

25. **WAIVER.** No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the party against whom the waiver is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

26. **CHOICE OF LAW.** This Agreement shall be construed and interpreted in accordance with the internal laws of the State of New Jersey without regard to its conflict of laws principles.

27. **LEGAL FEES.** In the event that there is a dispute under the terms of this Agreement, each party shall be responsible for its own legal fees and expense.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, effective as of the date first written above.

DBV Technologies, Inc.

By: /s/ Daniel Tasse

Daniel Tasse

Chief Executive Officer

Date: 06/13/19

By: /s/ Pharis Mohideen

Pharis Mohideen

Date: June 13, 2019

[English Translation]

Mr. Sébastien Robitaille

Montrouge, On June 26, 2019,

Mail delivered in person.

Dear Sébastien,

We are pleased to inform you that you are promoted to the position of Chief of Staff under the operational and functional authority of the CEO, effective July 1, 2019. The job description for this position is attached to this amendment.

Moreover, as from this date, your gross monthly remuneration will amount to €16,666.67 (sixteen thousand six hundred and sixty-six euros and sixty-seven cents).

Your open-ended employment contract is maintained in all its provisions not contrary to the present amendment.

In addition, your current duties as Deputy Chief Financial Officer will remain unchanged until the arrival of the Chief Financial Officer whose recruitment is underway.

Upon the arrival of the future Chief Financial Officer, it is agreed that you will cease your duties as Deputy Chief Financial Officer.

Please return one copy of each, dated, signed and preceded by the words “read and approved, good for agreement”.

Yours sincerely

Daniel Tassé
CEO

[English translation]

Mr. Sébastien Robitaille

Montrouge, On December 1, 2020,

Mail delivered in person.

Dear Sébastien,

We are pleased to inform you that you have been promoted to the position of Chief Financial Officer of DBV Technologies, under the operational and functional authority of the Chief Executive Officer, effective October 1, 2020.

In addition, your gross annual remuneration amounts to 220,000 euros (two hundred and twenty thousand euros) payable in twelve equal monthly instalments, i.e. an increase of 7.85%. This increase is retroactive to October 1, 2020.

The job description for this position is attached to this amendment.

Your permanent employment contract is maintained in all its provisions not contrary to this amendment.

I would be grateful if you could return a copy of this letter and the job description, dated, signed and preceded by the words “read and approved, good for agreement”.

Yours sincerely

Daniel Tassé
CEO

**Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Daniel Tassé, certify that:

1. I have reviewed this Annual Report on Form 10-K of DBV Technologies S.A.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 17, 2021

/s/ Daniel Tassé

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

**Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Sébastien Robitaille, certify that:

1. I have reviewed this Annual Report on Form 10-K of DBV Technologies S.A.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 17, 2021

/s/ Sébastien Robitaille

Name: Sébastien Robitaille

Title: Chief Financial Officer

(Principal Financial Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Daniel Tassé, Chief Executive Officer of DBV Technologies S.A. (the "Company"), and Sébastien Robitaille, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 17, 2021

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 17th day of March, 2021.

/s/ Daniel Tassé

Daniel Tassé
Chief Executive Officer

/s/ Sébastien Robitaille

Sébastien Robitaille
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of DBV Technologies S.A. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.