

Statement of Financial Position Data (in thousands, except share and per share data):

	As of December 31,					
	2014	2015	2016	2017	2018	
	Euros	Euros	Euros	Euros	Euros	US\$(1)
Cash and cash equivalents	114,583	323,381	256,473	137,880	122,770	140,645
Total assets	125,416	343,280	287,500	177,807	171,749	196,756
Total shareholders' equity	115,445	322,076	242,849	129,923	121,286	138,945
Total non-current liabilities	4,419	5,183	15,649	11,954	6,919	7,927
Total current liabilities	5,552	16,021	29,002	35,930	43,543	49,883
Total liabilities	9,971	21,204	44,651	47,884	50,463	57,810
Total liabilities and shareholders' equity	125,416	343,280	287,500	177,807	171,749	196,756

(1) Translated solely for convenience into dollars at the noon buying rate of the Federal Reserve Bank of New York of €1.00 = \$1.1456 at December 31, 2018.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

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 €114.5 million, €147.7 million and €166.1 million for the years ended December 31, 2016, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit and reserves of €421 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. While we have completed a pivotal Phase III trial to evaluate the safety and efficacy of Viaskin® Peanut, it may be a few years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a 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.

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 for our product candidates that successfully complete clinical trials, including Viaskin® Peanut;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, especially in North America;
- continue our research, pre-clinical and clinical development of our product candidates;
- expand the scope of our current clinical trials for our product candidates;
- initiate additional pre-clinical, clinical or other studies for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- 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;
- create additional infrastructure to support our operations as a public company; 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 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 and advance Viaskin® Milk through clinical development. 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 establish the appropriate infrastructure to commercialize.

As of December 31, 2018, our cash and cash equivalents were €122.8 million. We have primarily funded our operations through equity financings. To date, we have not generated any product revenue and we continue to prepare for the potential launch of our Viaskin® Peanut product candidate in North America planned in 2020 for which the BLA submission to the US FDA is expected in the third quarter of 2019. We expect operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support our operating plan for the next 12 months despite additional funds raised in March 2018. We expect to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding our ability to continue as a going concern. We expect to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

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.

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 launch and commercialization of Viaskin® Peanut in North America, if approved, or the commercialization of any other 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.

The Report Of Our Independent Registered Public Accounting Firm Contains An Explanatory Paragraph Regarding Substantial Doubt About Our Ability To Continue As A Going Concern.

The report of our independent registered public accounting firm on our audited financial statements as of and for the year ended December 31, 2018 contains an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. If we are unable to raise sufficient capital from our financing efforts to fund our operations as currently contemplated, we may need to significantly modify our operational plans for us to continue as a going concern or adjust the presentation of our financial statements to reflect that we may not be able to continue operating as a going concern. Further reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. If we cannot continue as a going concern, our investors may lose their entire investment.

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. As discussed further under "Item 10. B-Memorandum and Articles of Association," our board of directors may be precluded from issuing additional ordinary shares without first obtaining shareholders' approval.

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 June 22, 2018 granted authority to our board of directors to increase our share capital up to 20% 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.

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.

Our independent registered public accounting firm is also required, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting. This assessment includes 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, 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 Develop, Pursue Regulatory Approval For, And Commercialize, 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:

- progress in, 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, including Viaskin® Peanut;
- the costs of establishing, or contracting for, sales, marketing and distribution capabilities if we obtain regulatory approvals to market our product candidates, especially in North America;
- the scope, prioritization and number of our research and development programs;
- 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;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of securing manufacturing arrangements for commercial production.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through collaboration arrangements, sales of our securities, debt financings, obtaining public assistance in support of innovation, such as conditional advances from OSEO, and reimbursements of research tax credit claims, or by licensing one or more of our future product candidates. 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.

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 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 and may not result in product candidates 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 if we no longer qualify as a foreign private issuer. The Exchange Act requires that, as a public company, we file annual, semi-annual and current reports with respect to our business, financial condition and result of operations. However, as a foreign private issuer, we are not required to file quarterly reports with respect to our business, financial condition and results of operations. We currently make annual and semi-annual filings with respect to our listing on Euronext Paris. Unless otherwise required by the Exchange Act or the listing rules of the Nasdaq Global Select Market, we do not expect to file quarterly financial reports, but have and expect to continue to file financial reports on an annual and semi-annual basis. As a result of being a U.S. public company, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our

internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. 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 is also 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, our business and financial condition will become more visible, 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. While we plan to seek regulatory approval for Viaskin® Peanut, one of our two lead Viaskin® technology-based product candidates for which we have completed a pivotal Phase III trial, we cannot assure you that Viaskin® Peanut will successfully complete the FDA regulatory approval process and be commercialized. It is also possible that the FDA may require that we complete additional clinical trials of Viaskin® Peanut prior to considering Viaskin® Peanut for approval. Our other lead Viaskin® technology-based product candidate, Viaskin® Milk, is currently in clinical development. Our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of Viaskin® Peanut and Viaskin® Milk. 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 Viaskin® Peanut, Viaskin® Milk, or any other of our product candidates will be successfully developed or commercialized.

We are not permitted to market Viaskin® Peanut or Viaskin® Milk in the United States until we receive approval of a Biologics License Application, or a BLA, from the FDA, or in any other countries until we receive the requisite approval from such countries. Obtaining approval of a BLA, or requisite approval in other countries, is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of Viaskin® Peanut and Viaskin® Milk for many reasons, including, among others:

- we may not be able to demonstrate that Viaskin® Peanut or Viaskin® Milk is safe and effective in treating food allergies, to the satisfaction of the FDA;
- 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 for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may require that we conduct additional clinical trials;
- the FDA may not approve the formulation, labeling or specifications of either Viaskin® Peanut or Viaskin® Milk;
- 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 may find the data from pre-clinical studies and clinical trials from either Viaskin® Peanut or Viaskin® Milk insufficient to demonstrate that the clinical or other benefits of either product candidate outweighs its respective safety risks;
- the FDA may disagree with our analysis or interpretation of data from our pre-clinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our BLA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA 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 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.

In October 2017, we announced topline results from PEPITES, in which we observed a statistically significant response with a favorable tolerability profile. However, the primary endpoint, which evaluates the 95% confidence interval, or 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 trial's Statistical Analysis Plan submitted to the FDA. As such, any submission we make to the FDA or other regulatory agency for approval based on the PEPITES trial may be subject to such regulatory body's interpretation of the CI interval.

In October 2018, 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 December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls. Based on the progress in addressing the FDA's guidance, we anticipate compiling the required information for the submission of our BLA for Viaskin® Peanut in the third quarter of 2019. We cannot assure you that the BLA will be accepted for filing, will be approved or that we will not be required to conduct additional clinical trials of Viaskin® Peanut.

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 BLA may be submitted to the FDA. Although there are a large number of drugs and biologics in development in the United States and other countries,

only a small percentage result in the submission of an 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, Viaskin® Milk 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;
- 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.

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 a 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 BLAs 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. In October 2018,

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 December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls. Based on the progress in addressing the FDA's guidance, we anticipate compiling the required information for the submission of our BLA for Viaskin® Peanut in the third quarter of 2019. We cannot assure you that the BLA will be accepted for filing, will be approved or that we will not be required to conduct additional clinical trials of Viaskin® Peanut.

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 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.

A Breakthrough Therapy Designation By The FDA For Our Product Candidates May Not 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 breakthrough therapy designation for Viaskin® Peanut in children and we may pursue that designation for other product candidates as well. A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Such designation also offers an intensive and efficient review involving FDA senior managers and experienced review and regulatory health project management staff across disciplines. A breakthrough therapy designation affords the possibility of rolling review, enabling the FDA to review portions of our marketing application before submission of a complete application, and possibly, priority review. However, Viaskin® Peanut is an allergenic extract product that is not subject to the Prescription Drug User Fee Act, as amended, and accordingly, we may not receive priority review from the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that our product candidates, in addition to Viaskin® Peanut, meet the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification.

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. We may conduct clinical trials for, and seek regulatory approval to market, our 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 a European Marketing Authorization Application, or 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 a product candidate, 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 one or more of our 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 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;
- 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;
- our receipt of approvals, if any, by the FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, the trading price of the ADSs or ordinary shares may decline.

Access To Raw Materials And Products Necessary For The Conduct Of Clinical Trials And Manufacturing Of Our Product Candidates 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. The supply of these materials could be reduced or interrupted at any time. 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 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 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, such as peanut protein extract and unmodified allergen milk extract. If Sanofi cannot manufacture the active pharmaceutical ingredients as required by us in a timely manner, we may not be able to find a substitute manufacturer on a timely basis and our clinic trials may be delayed. Further, we are aware that Sanofi has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp (acquired by Merck), and Aimmune Therapeutics. 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 any 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.

We Or The Third Parties Upon Whom We Depend May Be Adversely Affected By Earthquakes Or Other Natural Disasters And Our Business Continuity And Disaster Recovery Plans May Not Adequately Protect Us From A Serious Disaster.

Earthquakes or other natural disasters 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 headquarters, 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.

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. We have not built commercial-scale manufacturing facilities, and we have limited manufacturing experience with Viaskin® patches.

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 May Enter Into Agreements With Third Parties To Sell And Market Any Products We Develop And For Which We Obtain Regulatory Approvals, Which May Affect The Sales Of Our Products And Our Ability To Generate Revenues.

Given our development stage, we have limited experience in sales, marketing and distribution of biopharmaceutical products. However, if our product candidates obtain marketing approval, we intend to develop sales and marketing capacity, either alone or with strategic partners by contracting with, or licensing, them to market any of our products. Outsourcing sales and marketing in this manner may subject us to a variety of risks, including:

- our inability to exercise control over sales and marketing activities and personnel;
- failure or inability of contracted sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- disputes with third parties concerning sales and marketing expenses, calculation of royalties, and sales and marketing strategies; and
- unforeseen costs and expenses associated with sales and marketing.

If we are unable to partner with a third party that has adequate sales, marketing and distribution capabilities, we may have difficulty commercializing our product candidates, which would adversely affect our business, financial condition and ability to generate product revenues.

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; and
- the market price of our product relative to competing treatments.

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 food allergy treatments. For example, Aimmune Therapeutics, Inc., or Aimmune, reported topline results from its Phase III trial evaluating the safety and efficacy of its OIT product candidate, AR101, in peanut allergic patients in February 2018. In March 2019, Aimmune announced that its BLA for AR101 was accepted for review by the FDA. To our knowledge, the company 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. We are also aware that Sanofi has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp., (acquired by Merck), and may pose a competitive risk to our products in the future. Aimmune also announced a clinical collaboration with Regeneron Pharmaceuticals, Inc. and Sanofi to study AR101 treatment with dupilumab in peanut allergic patients, and commenced a Phase II clinical trial in October 2018 under this collaboration. We believe that Regeneron and Sanofi are also planning to study 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 for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies. The companies plan to initiate a potentially pivotal trial in multiple food allergies. In March 2018, AnaptysBio, Inc. announced top-line proof-of-concept data for its ongoing Phase IIA trial to evaluate the safety of its IL-33 inhibitor product candidate, ANB020, in severe adult peanut allergic patients. In August 2018, AnaptysBio announced that it will deprioritize the development of ANB020 in peanut allergy.

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, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Additionally, 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. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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. While neither the Texas District Court Judge, Trump administration nor CMS have stated that the ruling will have an immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts 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's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation. The Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The United States Department of Health and Human Services has already started the process of soliciting feedback on some of these measures while concurrently implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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. ICER has announced that, in April 2019, it plans to publish a draft report assessing the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin® Peanut and a competitor product candidate. The results of the 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 anaphylaxis, skin and subcutaneous tissue, immune system and administration site conditions, such as erythema, pruritus, edema and urticaria. However, systemic reactions are a potential risk. 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 and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for, 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.
- 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, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. 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 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 and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.
- Analogous state, local or foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; 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, 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 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 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.

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 nonmisleading 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.

We May Not Obtain Biopharmaceutical Company Status And Therefore Have To Rely On Contract Manufacturers Indefinitely.

The French Drug and Health Products Safety Agency, or ANSM, has granted us the status of pharmaceutical establishment (*établissement pharmaceutique*), or PCS, solely for the purpose of conducting quality control activities at our Bagneux facility. There are two types of PCS: (1) "exploitant" status (*statut d'établissement pharmaceutique exploitant*), which permits medicines to be marketed directly in France by the company after demonstrating control of certain key functions such as pharmacovigilance, medical information and advertising, management of quality complaints and batch recall; and (2) manufacturer status, which permits the manufacturing and quality control of medicines after demonstrating adequate manufacturing and quality control premises that exhibit a quality assurance system that meets cGMP. Obtaining a pharmaceutical establishment license from the ANSM, either as an "exploitant" or as a manufacturer, requires the submission of a request file specific to each of the two qualifications with the ANSM. The ANSM grants PCS to a company upon evaluation and determination that such company's premises has adequate personnel, procedure and organization. Accordingly, we cannot manufacture or directly market in France the product candidates that we are developing.

We intend to seek an extension of our PCS manufacturer status to all manufacturing operations in order to have the ability to manufacture our product candidates. We also intend to seek "exploitant" status in order to market our products directly in France.

Failure to extend or obtain PCS status, as applicable, would force us to revise our strategy. First, failure to extend our manufacturer status to all manufacturing operations will force us to entrust the manufacturing and control of the therapeutic products to one or more specialized contract manufacturing organizations, or CMOs, as is the case with the current production of our clinical lots. Second, if "exploitant" status is not obtained, we will be unable to conduct a direct commercial approach to the French market and will therefore have to enter into marketing license agreements with other biopharmaceutical companies. Failure to extend or obtain either of the two types of PCS status, as applicable, would affect the production and marketing of our product candidates, once approved, and could be detrimental to our business, earnings, financial conditions and growth prospects.

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, and the clinical development of Viaskin® Milk, we may pursue development of our other development programs, including Viaskin® Egg and Viaskin® rPT. None of our other potential product candidates has commenced any clinical trials, 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 Viaskin® Milk 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 ADSSs. 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 Operation

We Will Need To Develop And Expand Our Company, And We May Encounter Difficulties In Managing This Development And Expansion, Which Could Disrupt Our Operations.

As of December 31, 2018, we had 315 full-time employees and we expect to significantly increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, including the commercialization of our product candidates in North America, we must continue 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 these development activities. 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. The 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.

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, such as our Chief Executive Officer, our Deputy Chief Executive Officer and our Responsible Pharmacist (qualified person). 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, including a full-time Chief Medical Officer, marketing, technical, and sales executives and personnel. The loss of any of our key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business.

We believe that equity ownership in our Company is important to provide our employees with long-term incentives in the development and performance of the Company by aligning the interests of our employees and managers with the interest of our shareholders. We use our free share plans as a motivation tool in order to retain and to attract talent. Granting of free shares is particularly important at this time of significant growth for our Company. Current French regulation limit the proportion of free shares that can be allocated to employees and managers to 10% of a company's share capital. Taking into account free shares plans already approved by us, this cap is almost reached, which prevents new allocations of free shares. In this context and in regards to equity compensation, attracting and

retaining key people could be more difficult. Furthermore, 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. 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. 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, 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 alleges that we and our former Chief Executive Officer, our current Chief Executive Officer and our

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 plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our securities between February 14, 2018 and December 19, 2018. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. However, 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 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 €7.2 million, €9.3 million and €10.8 million as of December 31, 2016, 2017 and 2018, 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, 2018, we have received multiple conditional advances totaling €6.2 million 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 Directive ((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, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Risks Related to Ownership of Our Ordinary Shares and ADSs

The Market Price For The 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 \$3.60 and as high as \$26.98 during 2018. During this same period, our ordinary share prices have ranged from as low as €7.59 to as high as €47.38. 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;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs and/or ordinary shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes in the structure of healthcare payment systems;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

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

Share Ownership Is Concentrated In The Hands Of Our Principal Shareholders And Management, Who Will Continue To Be Able To Exercise A Direct Or Indirect Controlling Influence On Us.

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, entities affiliated with Morgan Stanley, ArrowMark Colorado Holdings, LLC and entities affiliated with Boxer Capital, LLC, together beneficially own approximately 55.6% 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.

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. Please see the section of this Annual Report on Form 20-F titled “Item 10.B-Memorandum and Articles of Association” for further details on the limitations on our ability to declare and pay dividends. 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, 2018, 30,157,777 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.

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 French Banque de France. 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;
- the owner of 95% of 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; see the section of this Annual Report on Form 20-F titled "Item 10.B-Memorandum and Articles of Association";
- transfers of shares shall comply with applicable insider trading rules and regulations and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and

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

You May Not Be Able To Exercise Your Right To Vote The Ordinary Shares Underlying Your ADSs.

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

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

Your Right As A Holder Of ADSs To Participate In Any Future Preferential Subscription Rights Or To Elect To Receive Dividends In Shares May Be Limited, Which May Cause Dilution To Your Holdings.

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

You May Be Subject To Limitations On The Transfer Of Your ADSs And The Withdrawal Of The Underlying Ordinary Shares.

Your ADSs, which may be evidenced by ADRs, are transferable on the books of the 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.

As A Foreign Private Issuer, We Are Exempt From A Number Of Rules Under The U.S. Securities Laws And Are Permitted To File Less Information With The SEC Than A U.S. Company. This May Limit The Information Available To Holders Of Our ADSs.

We are a "foreign private issuer," as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Paris and we have and expect to continue to file financial reports on an annual and semi-annual basis, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. domestic issuers and are not required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there will be less publicly available information concerning our company than there would be if we were a U.S. domestic issuer.

As A Foreign Private Issuer, We Are Permitted To Adopt Certain Home Country Practices In Relation To Corporate Governance Matters That Differ Significantly From Nasdaq Corporate Governance Listing Standards. These Practices May Afford Less Protection To Shareholders Than They Would Enjoy If We Complied Fully With Corporate Governance Listing Standards.

As a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to corporate governance listing standards. However, rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in France, which is our home country, may differ significantly from corporate governance listing standards. For example, neither the corporate laws of France nor our by-laws require a majority of our directors to be independent and we could include non-independent directors as members of our compensation committee, and our independent directors do not necessarily hold regularly scheduled meetings at which only independent directors are present. Currently, we intend to follow home country practices to the maximum extent possible. Therefore, our shareholders may be afforded less protection than they otherwise would have under corporate governance listing standards applicable to U.S. domestic issuers.

We May Lose Our Foreign Private Issuer Status In The Future, Which Could Result In Significant Additional Cost And Expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2019, which would require us to comply with all of

the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2020. We could lose our foreign private issuer status in the future if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares or ADSs must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50% of our assets cannot be located in the United States and (iii) our business must not be administered principally inside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. As of December 31, 2018, approximately 53% of our outstanding ordinary shares were held by U.S. residents.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we currently incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, and in U.S. dollars rather than euros, and to modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP will involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

U.S. Investors May Have Difficulty Enforcing Civil Liabilities Against Our Company And Directors And Senior Management And The Experts Named In This Annual Report.

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. See the sections of this Annual Report on Form 20-F titled "Item 10. B-Memorandum and Articles of Association" and "Item 16.G-Corporate Governance."