Risk Factors Comparison 2025-04-11 to 2024-03-07 Form: 10-K

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Investing in our securities involves a high degree of risk. The following information about these risks, together with the other information appearing elsewhere in this Annual Report on form 10- K, including our consolidated financial statements and related notes thereto and management' s discussion and analysis of financial condition and results of operation, should be carefully considered before a decision to invest in our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. Additional risks that are currently unknown to us or that we currently believe to be immaterial may also impair our business. In these circumstances, the market price of our securities could decline, and holders of our securities may lose all or part of their investment. We cannot provide assurance that any of the events discussed below will not occur. Risks Related to Our Financial Condition and Capital Requirements We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We are a clinical- stage biopharmaceutical company, and we have not yet generated significant income from operating activities. We have incurred net losses in each year since our inception in 2002, including net losses of $ **113. 9 million and $** 72. **7** ~~7million and $ 96. 3~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of $ ~~238~~ **286**. ~~9~~ **4** million. We have devoted most of our financial resources to research and development, including our clinical and pre-clinical development activities. To date, we have financed our operations primarily through the sale of equity securities, obtaining public assistance in support of innovation, such as conditional advances from OSEO Innovation, or OSEO, reimbursements of research tax credit claims and strategic collaborations. The amount of our future net losses will depend, in part, on the pace and amount of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or additional grants or tax credits. To date, we have not generated any product revenue and we continue to advance the clinical and regulatory development of Viaskin Peanut in the United States and European Union. Even if we obtain regulatory approval to market Viaskin Peanut or any other product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third- party payors and adequate market share for any approved products in those markets. Our near- term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of Viaskin Peanut. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we: • seek regulatory approvals and pursue commercial activities for Viaskin Peanut, and for which we continue to seek regulatory approvals in the United States; • continue our research, pre- clinical and clinical development of our product candidates, including additional trials related to our pursuit of regulatory approval of Viaskin Peanut in the United States; • seek regulatory approvals for our other product candidates that successfully complete clinical trials; • establish a sales, marketing and distribution infrastructure to commercialize Viaskin Peanut, if approved, and any other products for which we may obtain regulatory approval, especially in North America; • further develop the manufacturing process for our product candidates, including any modifications to our patch technology; • change or add additional manufacturers or suppliers; • expand the scope of our current clinical trials for our product candidates; • initiate and conduct any post- approval clinical trials, if required by the FDA or comparable foreign regulatory authorities, for our approved products, if any; • initiate additional pre- clinical, clinical or other studies for our other product candidates; • seek to identify and validate additional product candidates; • acquire or in-license other product candidates and technologies; • make milestone or other payments under any in- license agreements; • maintain, protect and expand our intellectual property portfolio; • attract and retain new and existing skilled personnel; • add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts, as well as a company listed on both the U. S. and French stock markets; and • experience any delays or encounter issues with any of the above. The net losses we incur may fluctuate significantly from year to year, such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. In any particular period or periods, our operating results could be below the expectations of securities analysts or investors, which could cause the price of our ADSs or ordinary shares to decline. ~~Based on our current operations, as well as our plans and assumptions, we expect that our balance of cash and cash equivalents of $ 141. 4 million as of December 31, 2023 will be sufficient to fund our operations until December 31, 2024.~~ The ~~company~~ **Company** has incurred operating losses and negative cash flows from operations since inception. ~~As of~~ **Subsequent to December 31, 2024,** the **Company raised additional proceeds in a private placement financing (the " 2025 PIPE ") consisting of i) a share capital increase without preferential subscription rights reserved to categories of persons satisfying determined characteristics pursuant to the 24th resolution of the general meeting of shareholders of May 16, 2024 (the" 2024 General Meeting") completed on April 7, 2025 for an amount of € 38 million, consisting of the issuance of (i) 34, 090, 004 new shares at a par value of € 0. 10 (the" New Shares") each with warrants of the Company attached (the" ABSA Warrants", and together with the New Shares, the" ABSA") at a subscription price of € 1. 1136 per ABSA and (ii) up to 59, 657, 507 additional new shares, if all the ABSA Warrants attached to the New Shares are exercised (the" ABSA Warrant Shares"); and ii) the issue through an offering reserved to categories of persons satisfying determined characteristics of 71, 005, 656 units (the " PFW- BS- PFW ") completed on April 7, 2025 for an amount of € 79 million at a subscription price of € 1. 1136 per**

PFW- BS- PFW (of which € 1. 1036 will have been prefunded on the issue date **)** ~~of the filing~~ , **each PFW- BS- PFW consisting of one pre- funded warrant to subscribe for one share of the Company (the" First Pre- Funded Warrants") and one warrant (the" BS Warrants") to subscribe to one second pre- funded warrants (the" Second Pre- Funded Warrants"), each of which entitles the holder to subscribe for 1. 75 shares of the Company (the" Second PFW Shares"), allowing to issue up to 71, 005, 656 additional new shares if all the First Pre- Funded Warrants are exercised (the" First PFW Shares") and up to 124, 259, 898 additional new shares if all the Second Pre- Funded Warrants are exercised (the" Second PFW Shares", together with the ABSA Warrant Shares and the First Pre- Funded Warrant Shares, the" Warrant Shares", and together with the New Shares, the" Offered Shares"). The Company received initial net proceeds of $ 125. 5 million (€ 116. 3 million) on April 7, 2025, and based on** our ~~available~~ **current operations, plans and assumptions, we estimate that our balance of** cash ~~is not projected to~~ **and cash equivalents will** be sufficient to ~~support~~ **fund** our ~~operating~~ **operations into June 2026** ~~plan for at least the next 12 months. As such, there is substantial doubt regarding our ability to continue as a going concern~~ . We ~~intend to seek~~ **further estimate that, following the potential issuance of all Warrant Shares in the financing, representing potential** additional ~~capital as~~ **gross proceeds of up to $ 181. 4 million (€ 168. 2 million),** we ~~prepare for the launch~~ **could extend our financial visibility into 2028 and through potential commercialization** of Viaskin Peanut **in the U. S** , if approved ~~, and continue other research and development efforts. The Company will require substantial additional capital to fund its 44 research and development and ongoing operating expenses. The Company will seek to fund these capital requirements through debt and public or private equity before December 31, 2024. We intend to seek additional capital as we prepare for the launch of Viaskin Peanut, if approved, and continue other research and development efforts. We may seek to finance our future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non- dilutive financings. We cannot guarantee that we will be able to obtain the necessary financing to meet our needs or to obtain funds at attractive terms and conditions, including as a result of disruptions to the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to us, including reduced ability to raise additional capital when needed or on acceptable terms, if at all. If we are not successful in our financing objectives, we could have to scale back our operations, notably by delaying or reducing the scope of our research and development efforts or obtain financing through arrangements with collaborators or others that may require us to relinquish rights to our product candidates that we might otherwise seek to develop or commercialize independently. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations~~ . We will require substantial additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations. We are currently advancing our product candidates through pre- clinical and clinical development. Developing product candidates is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we seek regulatory approval for Viaskin Peanut. Furthermore, if we obtain regulatory approval for Viaskin Peanut or any other product candidate that we may develop, we expect our commercialization expenses related to product sales, marketing, distribution and manufacturing to increase significantly as we develop the appropriate infrastructure to commercialize. In addition, our expenses could increase beyond expectations if the FDA requires us to perform nonclinical studies, clinical trials or post- approval clinical trials for our approved products, if any, in addition to those that we currently anticipate. As of December 31, ~~2023~~ **2024** , our cash and cash equivalents were $ ~~141~~ **32** . ~~4~~ **5** million. Since our inception, we have primarily funded our operations with equity financings, and, to a lesser extent, public assistance aimed at supporting innovation and payments associated with research tax credits (~~Crédit~~ **crédit** d' ~~Impôt~~ **impôt** ~~Recherche~~ **recherche**). We do not generate product revenue and continue to prepare for the potential launch of our first product in the United States and in the European Union, if approved. Based on our current operations, as well as our plans and assumptions, we expect that our balance of cash and cash equivalents of $ ~~141, 4~~ **32. 5** million as of December 31, ~~2023~~ **2024** will be sufficient to fund our operations ~~until~~ **into April 2025. Subsequent to** December 31, 2024 **, the Company raised additional proceeds in the 2025 PIPE of initial net proceeds of $ 125. 5 million (€ 116. 3 million) received on April 7, 2025, and based on our current operations, plans and assumptions, we estimate that our balance of cash and cash equivalents will be sufficient to fund our operations into June 2026** . We ~~expect~~ **further estimate** that **, following the potential issuance of all Warrant Shares in the financing, representing potential additional gross proceeds of up to $ 181. 4 million (€ 168. 2 million),** we ~~will~~ **could extend our financial visibility into 2028 and through potential commercialization of Viaskin Peanut in the U. S, if approved. We may** need to raise ~~substantial~~ additional capital as we prepare for the launch of Viaskin Peanut, if approved, and continue other research and development efforts. We may seek to finance our future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non- dilutive financings. ~~45~~ We cannot guarantee that we will be able to obtain the necessary financing to meet our needs or to obtain funds at attractive terms and conditions, including as a result of disruptions to the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to us, including reduced ability to raise additional capital when needed or on acceptable terms, if at all. If we cannot conduct necessary operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected. Additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs or ordinary shares to decline.

The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain sufficient funding on a timely basis, we may be required to scale back our operating plan, significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. We are limited in our ability to raise additional share capital, which may make it difficult for us to raise capital to fund our operations. Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (délégation de compétence) or the power (délégation de pouvoir) to carry out any increase in share capital. In addition, the French Commercial Code imposes certain limitations on our ability to price any offering of our share capital without preferential subscription right (sans droit préférentiel de souscription), which limitation may prevent us from successfully completing any such offering. Specifically, under the French Commercial Code, unless the offering is less than 10 % of issued share capital, securities cannot be sold in an offering at a price that is more than a 10 % discount to the volume weighted average trading price on Euronext Paris over the last three trading days preceding the commencement of the marketing of the transaction. In addition, the combined shareholders' meeting dated ~~April 12~~ **May 16** , ~~2023~~ **2024** granted authority to our board of directors to increase our share capital up to 100 % of issued share capital, if the investors in such offering fit within categories of persons meeting certain characteristics. In this case securities cannot be sold in such an offering at a price that is more than a 15 % discount to (i) the last closing price of the Company' s shares on the regulated market Euronext Paris prior to the date on which the issue price is set, (ii) the volume-weighted average price of the share of the Company on the regulated market of Euronext Paris over a period determined by the Board of Directors of between one to five consecutive trading days chosen from the last thirty trading days prior to the date on which the issue price is set. ~~46~~ Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises ~~such as the COVID- 19 pandemic~~ , political crises, geopolitical events ~~, such as the crisis in Ukraine and the Israel- Hamas war~~ , or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability ~~. For example~~ , **due to reasons including, among** ~~the~~ **other** ~~COVID- 19 pandemic resulted in widespread unemployment~~ **things, political changes and trends such as protectionism** , economic **nationalism** ~~slowdown and extreme volatility in the capital markets. As a result~~ **resulting** ~~of the COVID- 19 pandemic,~~ **in government actions impacting international trade agreements** ~~our~~ **or imposing trade restrictions such** ~~ability to conduct clinical trials was~~ **as** ~~affected~~ **tariffs and retaliatory counter measures. The U. S. Government, including the FDA, has also experienced recent challenges in personnel staffing related to the new administration, which personnel shortages could adversely impact the review and responsiveness on INDs or BLAs** . Future pandemics, epidemics or other public health crises (collectively, " public health crises ") could have an impact on our ability to conduct clinical trials, and clinical site initiation, subject enrollment and subject visits (including food challenges) in any of our clinical trials may be suspended or delayed due to prioritization of hospital resources toward responding to such public health crises. Some participants may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers may adversely impact our future clinical trial operations. **Any** ~~The COVID- 19 pandemic and related government and private sector responsive actions affected, and any~~ future public health crises could affect, the broader economies and financial markets, triggering an economic downturn, which at points adversely affected or could adversely affect, our ability to access capital, which could negatively affect our business. In addition, the recession or resulting adverse impacts on the capital markets resulting from ~~the COVID- 19 pandemic, and~~ any future public health crises, could materially affect our business. The U. S. Federal Reserve **has in** ~~recently~~ -- **recent years** raised interest rates multiple times in response to concerns about inflation and it may raise them again. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs. Our business could be materially and adversely affected by the effects of any future public health crises in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations. Any future public health crises could materially affect our operations as well as cause significant disruption in the operations and business of third- party manufacturers, CROs, other services providers, and collaborators with whom we conduct business. It is impossible to predict all effects and the ultimate impact of any public health crises ~~, including the COVID- 19 pandemic~~ . The full extent **of** the impact of any future public health crises on our clinical development and other operations and financial performance depends on continuing developments that are uncertain and unpredictable, including the timing of any future vaccine development and rollouts and herd immunity, virus mutations and variants, and any new information that may emerge concerning future virus, vaccines, and containment, all

of which may vary across regions. Any of these factors could have a material adverse impact on our business, financial condition, operating results, and ability to execute and capitalize on our strategies. On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the United States and other countries and companies and organizations against officials, individuals, regions, and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and responses of countries and ~~47~~ political bodies to such sanctions, tensions, and military actions and the potential for more widespread conflict, have resulted in supply chain disruptions, and resulting increases in inflation, financial market volatility and capital markets disruption, potentially increasing in magnitude, and such effects on the global economy and financial markets could affect our business, operations, operating results and financial condition as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms. Separately, in early October 2023, Hamas, a militant group in control of Gaza, and Israel began an armed conflict in Israel, the Gaza Strip, and surrounding areas, which threatens to spread to other Middle Eastern countries, including Lebanon, Syria, and Iran. The Hamas- Israel military conflict is ongoing, and its length and outcome are highly unpredictable. Any or all of the effects of these conflicts could disrupt our and our collaborators' supply chains and adversely affect our and our collaborators' ability to conduct ongoing and future clinical trials of our product candidates. The extent and duration of the military action, sanctions and resulting economic, market and other disruptions are impossible to predict, but could be substantial. Any such disruptions may magnify the impact of the other risks described in this report. We are obligated to develop and maintain a system of effective internal controls over financial reporting. These internal controls may be determined to be not effective, which may adversely affect investor confidence in our company and, as a result, the value of our ordinary shares and ADSs. We have been and are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on an annual basis. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective and would be required to disclose any material weaknesses identified in Management' s Report on Internal Control over Financial Reporting. While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will prevent restatements of our financial statements in the future. Depending on our future filer status with the SEC, our independent registered public accounting firm may also require, pursuant to Section 404 of the Sarbanes- Oxley Act, to report on the effectiveness of our internal control over financial reporting. ~~This assessment will include disclosure of any material weaknesses identified by our management in our internal control over financial reporting.~~ For future reporting periods, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective if and when a report from such accounting firm is required, investors could lose confidence in the accuracy and completeness of our financial reports, which could cause the price of our ordinary shares and ADSs to decline, and we could be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Failure to remediate any material weakness in our internal control over financial reporting, or to maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. ~~48~~ If we do not obtain the capital necessary to fund our operations, we will be unable to successfully commercialize, develop or pursue regulatory approval for our biopharmaceutical products. The development of biopharmaceutical products is capital- intensive. We anticipate that we will require additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including: • the scope, progress in, results and the costs of, our pre- clinical studies and clinical trials and other research and development programs, particularly as we seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials; • the approval of Viaskin Peanut by the FDA, European Commission, or other comparable regulatory authorities; • the costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive regulatory approval, especially in North America; • the costs of securing manufacturing arrangements for commercial production; • revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive regulatory approval; • the scope, prioritization and number of our research and development programs; • the costs, timing and outcome of regulatory review of our product candidates; • the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements, and any additional collaboration agreements we may enter into; • the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under our existing collaboration agreements and future collaboration agreements, if any; and • the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights. Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non- dilutive financings. Uncertainty and dislocations in the financial markets have generally made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our future fundraising needs. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding, if obtained, may significantly dilute existing shareholders if that financing is obtained through issuing equity or instruments convertible into equity. We could also be required to seek funds through

collaborations or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. The requirements of being a U. S. public company may strain our resources, divert management' s attention and affect our ability to attract and retain executive management and qualified board members. As a U. S. public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. We are subject to the reporting requirements of the Securities ~~49~~ Exchange Act of 1934, or the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations will continue to increase our legal and financial compliance costs, make some activities more difficult, time- consuming or costly and increase demand on our systems and resources, particularly as we now qualify as a domestic filer. The Exchange Act requires that, as a public company that no longer qualifies as a foreign private issuer, we file annual, quarterly and current reports with respect to our business, financial condition and result of operations. Because we are no longer a foreign private issuer, we will also be required to file proxy statements in connection with any meetings of our shareholders. As a result of being a U. S. public company, management' s attention may be diverted from other business concerns, which could adversely affect our business and results of operations. The Sarbanes- Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. Compliance with Section 404 may require that we incur substantial accounting expenses and expend significant management efforts. Our independent registered public accounting firm may also be required, pursuant to Section 404 of the Sarbanes- Oxley Act, to report on the effectiveness of our internal control over financial reporting. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective, the market price of our ordinary shares and ADSs could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC or other applicable regulatory authorities and our business could be harmed. As a U. S. public company that is subject to these rules and regulations, we may find it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers. As a result of disclosure of information in filings required of a U. S. public company, particularly as we are no longer a foreign private issuer, our business and financial condition will become more visible than they would be if we were a privately- owned company or if our securities were listed only on Euronext Paris, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and results of operations. Further, being both a U. S. public company and a French public company has an impact on disclosure of information and compliance with two sets of applicable rules. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Risks Related to Product Development, Regulatory Approval and Commercialization We depend almost entirely on the successful development of our novel Viaskin technology. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, Viaskin products. We currently have no drug or biological product approved for sale and may never be able to develop a marketable drug or biological product. ~~50~~ We may not be successful in developing and commercializing Viaskin Peanut and our other product candidates, including, without limitation, Viaskin Milk, and our commercial opportunities may be limited. We are currently conducting VITESSE, a Phase 3 pivotal study in children aged 4 through 7 years of age with confirmed diagnosis of peanut allergy with Type V Viaskin Peanut System, or the modified Viaskin Peanut system. Additionally, we **are planning one** ~~intend to carry out two~~ additional Phase 3 safety ~~studies~~ **study** in response to the FDA' s request regarding the size of the controlled safety database. ~~One~~ **This safety** study will be conducted in ~~peanut allergic children 4 through 7 years of age using the Type Viaskin Peanut System (mVP), and the other will focus on~~ peanut allergic children 1 through 3 years of age ~~with~~ **using** the Type IV Viaskin Peanut **Epicutaneous** System (the ~~original~~ **planned commercial** Viaskin Peanut system **in this age group** , or cVP). **Lastly, in connection with the Accelerated Approval pathway for Viaskin Peanut in toddlers 1 – 3- years- old we will need to complete a post- marketing confirmatory study to assess the effectiveness of the intended commercial Viaskin Peanut patch that will need to be initiated at the time that the BLA is submitted.** Positive results in ~~all these~~ -- **the** studies ~~are~~ **will be** imperative for us to seek regulatory approval before we are permitted to commence commercialization, if ever **. The confirmatory study must also be positive post- approval or the FDA may likely seek withdrawal of approval of Viaskin Peanut in the 1- 3- year- old age group** . Viaskin Milk will also require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence its commercialization, if ever. Many of our other product candidates are still in pre- clinical or early proof- of- concept phase development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if

approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that, among other things, the product candidate is safe and effective for use in each target indication. This process can take many years and may include post- marketing requirements and surveillance, including the completion of pediatric clinical trials to satisfy both U. S. and EU requirements, which will require the expenditure of substantial resources. Of the large number of drugs in development in the United States, only a small percentage successfully completes the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be approved by relevant regulators or will be successfully developed or commercialized. In addition, in some jurisdictions such as the EU, initiating Phase 3 clinical trials, including clinical trials in the pediatric population, is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and / or the EMA. If we do not obtain such approval our ability to conduct clinical trials and obtain marketing authorizations may be severely impaired and our business may be adversely impacted. We are not permitted to market any of our product candidates in the United States or in any other country until we receive the requisite approval from the applicable regulators. Obtaining requisite regulatory approval in any country is a complex, lengthy, expensive and uncertain process, and the FDA or the applicable foreign regulatory authority may delay, limit or deny approval of a Viaskin product, for many reasons, including, among others: • we may not be able to demonstrate that a product candidate is a safe and effective treatment, to the satisfaction of the FDA or the applicable foreign regulatory authority; • the results of our clinical trials or the clinical trials conducted by third party academic institutions and included in our application package may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory authority for regulatory approval; • the FDA or the applicable foreign regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials; • the FDA or the applicable foreign regulatory authority may require that we conduct additional clinical trials; • the FDA or the applicable foreign regulatory authority may not approve the formulation, labeling or specifications of a product candidate; • the clinical research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials; ~~51~~ • the FDA or the applicable foreign regulatory authority may find the data from pre- clinical studies and clinical trials from a product candidate insufficient to demonstrate that the clinical or other benefits of such product candidate outweighs its respective safety risks; • the FDA or the applicable foreign regulatory authority may disagree with our analysis or interpretation of data from our pre- clinical studies and clinical trials; • the FDA or the applicable foreign regulatory authority may not accept data generated at our clinical trial sites; • an advisory committee, or similar body, may recommend against approval of our application or may recommend that the FDA or the applicable foreign regulatory authority require, as a condition of approval, additional pre- clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; • the FDA or the applicable foreign regulatory authority may require development or implementation of a Risk Evaluation and Mitigation Strategy (or REMS), or comparable foreign requirements, as a condition of approval or post- approval; • the FDA or the applicable foreign regulatory authority may restrict the use of our products to a narrow population; • the FDA or the applicable foreign regulatory authority may not approve the manufacturing processes or facilities of our own or of third- party manufacturers with which we contract, or may issue inspectional findings that require significant expense and time to address; or • the FDA or the applicable foreign regulatory authority may change their approval policies or new legislation governing the approval processes. Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any of our product candidates based on our Viaskin technology platform. Moreover, because our business is almost entirely dependent upon our Viaskin technology, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects. Our product candidates have undergone and / or will be required to undergo clinical trials that are time- consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulatory authorities, we, or our collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates. Pre- clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre- clinical testing and clinical development necessary to commercialize a drug or biologic, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in pre- clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical, biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after positive results in earlier trials, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support regulatory approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major setback for our product candidates and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business and financial condition and on the value of our ADSs and ordinary shares. ~~52~~ In connection with clinical testing and trials, we face a number of risks, including, but not limited to: • a product candidate is ineffective, inferior to existing approved medicines or treatment options, unacceptably toxic, or has unacceptable side effects; • patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested, especially during the double- blind, placebo-controlled food challenges; • extension studies on long- term tolerance could invalidate the use of our product, showing Viaskin does not generate a sustained protective effect; • any positive results of earlier testing or trials may not be confirmed by results of subsequent trials; and • the results may not meet the level of statistical significance required by the FDA or other comparable

regulatory authorities to establish the safety and efficacy of our product candidates. The results of pre- clinical studies do not necessarily predict clinical success, and larger and later- stage clinical trials may not produce the same results as earlier- stage clinical trials. As a result, we may not observe a similarly favorable safety and efficacy profile as our prior clinical trials. For example, in August 2020, we received a Complete Response Letter, or CRL, in which the FDA indicated it could not approve the Viaskin Peanut BLA in its then- current form. The FDA identified concerns regarding the impact of system adhesion on efficacy and indicated the need for modifications, and new human factors studies. The FDA also indicated that supplementary clinical data would need to be generated to support applications for both the Type IV Viaskin Peanut System ~~(the original Viaskin Peanut system)~~ , or cVP, and the Type V Viaskin Peanut System (the modified Viaskin Peanut System), or mVP, and requested additional Chemistry, Manufacturing and Controls, or CMC, data. Further, in September 2022, we announced that FDA had imposed a partial clinical hold on the VITESSE trial, which was lifted in December 2022 after we made additional revisions to the protocol in order to address FDA concerns. In addition, we cannot assure you that in the course of potential widespread use in future, some drawbacks would not appear in maintaining production quality, protein stability or allergenic strength. Frequently, product candidates developed by pharmaceutical, biopharmaceutical and biotechnology companies have shown positive results in early pre- clinical studies or clinical trials, but have subsequently suffered significant setbacks or failed in later clinical trials. In addition, clinical trials of potential products sometimes reveal that it is not possible or practical to continue development efforts for these product candidates. If we do not successfully complete pre- clinical and clinical development, we will be unable to market and sell our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an application for regulatory approval may be submitted to the FDA or a comparable foreign regulatory authority. Although there are a large number of drugs and biologics in development in the United States and other countries, only a small percentage result in the submission of an application for regulatory approval to a regulatory authority, such as an NDA or a BLA to the FDA, or comparable foreign regulatory authorities, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed. In many of clinical trials, we utilize an oral food challenge procedure intentionally designed to trigger an allergic reaction, which could be severe or life- threatening. In accordance with our food allergy clinical trial protocols, we utilize a double- blind, placebo-controlled food challenge procedure at various points in our clinical trials. This consists of giving the offending food protein to subjects to assess the sensitivity of their food allergy to determine eligibility to participate and to evaluate the efficacy of our product candidates versus placebo. The food challenge protocol is meant to induce objective symptoms of an allergic reaction. These oral food challenge procedures can potentially trigger anaphylaxis or potentially life- threatening systemic allergic ~~53~~ reactions. Even though these procedures are well- controlled, standardized and performed in highly specialized centers with intensive care units, there are inherent risks in conducting a trial of this nature. An uncontrolled allergic reaction could potentially lead to serious or even fatal reactions. Any such serious clinical event could potentially adversely affect our clinical development timelines, including a complete clinical hold on our food allergy clinical trials. We may also become liable to subjects who participate in our clinical trials and experience any such serious or fatal reactions. Any of the foregoing could have a material adverse effect on our business, prospects, stock price or financial condition. Delays, suspensions and terminations in our clinical trials could result in increased costs to us and delay or prevent our ability to generate revenues. Human clinical trials are very expensive, time- consuming, and difficult to design, implement and complete. The completion of trials for Viaskin Peanut and our other product candidates may be delayed for a variety of reasons, including, but not limited to, delays in: • demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial; • reaching agreement on acceptable terms with prospective CROs, and clinical trial sites; • validating test methods to support quality testing of the drug substance and drug product; • obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials; • manufacturing sufficient quantities of a product candidate; • obtaining timely responses from and permission to proceed from the FDA under an investigational new drug, or IND, application, or foreign equivalent approval from regulatory authorities outside the United States; • obtaining institutional review board, or IRB, approval or positive Ethics Committee opinions as part of the single decision on the authorization of a clinical trial issued by EU Member States including input from the national competent authority and Ethics Committee, to conduct a clinical trial at a prospective clinical trial site; • determining dosing and clinical design and making related adjustments; and • subject enrollment, which is a function of many factors, including the size of the population, the nature of the protocol, the proximity of participants to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. The commencement and completion of clinical trials for our product candidates may be delayed, suspended or terminated due to a number of factors, including: • lack of effectiveness of product candidates during clinical trials; • adverse events, safety issues or side effects relating to the product candidates or their formulation; • serious adverse events relating to the double- blind, placebo- controlled food challenge procedure when testing participants for the sensitivity of their allergies; • inability to **provide clinical supplies or product candidate necessary for the conduct of clinical trials due to shortages or unavailability; • delays in lab testing of product candidates required for release for use in clinical trials; • inability to** raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive; • the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources; • our inability to enter into collaborations relating to the development and commercialization of our product candidates; • failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements; ~~54~~ • our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre- clinical studies and clinical trials; • governmental or regulatory delays, changes by regulatory agencies, including, without limitation, unexpected changes, unrelated to new developments of the science, in

prior guidance and instruction provided to us, changes in regulatory requirements, policy and guidelines, and mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results; • failure of our collaborators to advance our product candidates through clinical development; • delays in enrollment, variability in the number and types of subjects available for clinical trials, and lower- than anticipated retention rates for subjects in clinical trials; • difficulty in subject monitoring and data collection due to failure of subjects to maintain contact after treatment; • a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as the COVID- 19 pandemic or any other pandemics, epidemics, or global health crises, terrorist activities or war, or a natural disaster; and • varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory authorities. For example, we announced in September 2022 that FDA had imposed a partial clinical hold on the VITESSE trial, which was lifted in December 2022, resulting in a delay in initiation and conduct of the VITESSE trial. Many of these factors may also ultimately lead to denial of our applications for regulatory approval for our product candidates. If we experience delay, suspensions or terminations of a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed or such revenues could be reduced or fail to materialize. In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, resource constraints or changes in resources at the regulatory agencies tasked with reviewing our submissions, resulting in delays in receiving timely and consistent guidance, or changes in FDA or other similar foreign regulatory authority policy or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn, varied or suspended. Delays or failures in obtaining regulatory approvals may result in: • varying interpretations of data and commitments by the FDA and similar foreign regulatory authorities; and • diminishment of any competitive advantages that such product candidates may have or attain. Furthermore, if we fail to comply with applicable FDA and other regulatory requirements at any stage during this regulatory process, we may encounter or be subject to: • issuance of warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available; • diminishment of any competitive advantages that such product candidates may have or attain; • suspension, delays or termination in clinical trials or commercialization; • delays or refusal by the FDA or similar foreign regulatory authorities to review pending applications for regulatory approval or supplements to approved applications; • voluntary or mandatory product recalls or seizures; • refusal to permit the import or export of medicinal products or intermediary chemicals; • suspension, restrictions or additional requirements on operations, including of manufacturing or revocation of necessary licenses; ~~55~~ • withdrawals, variations or suspensions of regulatory approvals; and • fines, civil penalties, and criminal prosecutions. If our product candidates are not approved by the FDA, or comparable foreign regulatory authorities, we will be unable to commercialize them in the United States or in other countries. The FDA must approve any new drug or biologic before it can be commercialized, marketed, promoted or sold in the United States. We must provide the FDA with data from pre- clinical studies and clinical trials that demonstrate that, among other things, our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. There is significant competition to secure clinical trial support resources, including CROs. Clinical sites are resource constrained with the availability of these sites further limited due to, in certain instances, participation in multiple clinical trials. In addition, there are various opportunities for subjects eligible to participate in our clinical trials to participate in other food allergy clinical trials or allergy related trials. We must provide data to ensure the identity, strength, quality and purity of the drug substance and drug product. Also, we must assure the FDA that the characteristics and performance of the clinical batches will be replicated consistently in the commercial batches. We will not obtain approval for a product candidate unless and until the FDA approves a BLA, if at all. The processes by which regulatory approvals are obtained from the FDA to market and sell a new or repositioned product are complex, require a number of years and involve the expenditure of substantial resources. We have already experienced several setbacks and delays in our previously anticipated ability to obtain approval of Viaskin Peanut from the FDA and the European Commission, and we may experience additional delays in the future. We cannot assure you that any of our product candidates will receive FDA approval, or regulatory approval from a comparable foreign regulatory authority, in the future, and the time for receipt of any such approval is currently incapable of estimation. A Fast Track designation by the FDA, or equivalent foreign programs, may not actually lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive regulatory approval. We have obtained Fast Track designation from the FDA for the development of Viaskin Peanut and Viaskin Milk, and we may apply for that designation for other product candidates as well. If a product is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation. The FDA has broad discretion to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do have Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Generally, a Fast Track designation affords the possibility of rolling review, enabling the FDA to review portions of our marketing application before submission of a complete application. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. The regulatory approval process outside the United States varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad. In order to market and sell our product candidates in the European Union and many other jurisdictions, we, and our collaborators, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may, in the future, conduct clinical trials for, and seek regulatory approval to market, product candidates in countries other than the United States. Depending on the results of

clinical trials and the process for obtaining ~~56~~ regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the United States, or we may simultaneously seek regulatory approvals in the United States and other countries. If we or our collaborators seek marketing approvals for a product candidate outside the United States, we will be subject to the regulatory requirements of health authorities in each country in which we seek approvals. With respect to marketing authorizations in the European Union, we will be required to submit an MAA to the EMA which conducts a validation and scientific review process in evaluating a product for safety and efficacy. The regulatory approval procedures vary among countries and may involve additional testing, and the time required to obtain approvals may differ from that required to obtain FDA approval. Pursuing regulatory approvals from regulatory authorities in countries outside the United States is likely to subject us to all of the risks associated with pursuing FDA approval described above. In addition, regulatory approval by the FDA does not ensure approval by the regulatory authorities of any other country, and approval by foreign regulatory authorities does not ensure regulatory approval by the FDA. Even if we, or our collaborators, obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or they market our products, which could materially impair our ability to generate revenue. Even if we receive regulatory approval for Viaskin Peanut or any of our other product candidates, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or limit the patient population that may utilize the product or require a product to carry a warning in its labeling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive regulatory approval for Viaskin Peanut or any of our other product candidates, we and our collaborators will continue to expend time, money and effort in all areas of regulatory compliance. Any of our product candidates for which we, or our collaborators, obtain regulatory approval in the future could be subject to post- marketing requirements, post- marketing commitments or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval. Any of our product candidates for which we, or our collaborators, obtain regulatory approval in the future, as well as the manufacturing processes, post- marketing requirements and commitments, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other foreign regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product candidate is granted, the approval will be subject to limitations on the indicated uses for which the product may be marketed or may be subject to other conditions of approval, including **, without limitation, FDA requirement that we pre- clear all promotional materials with the agency and** the FDA requirement to implement a REMS, or comparable foreign requirements to ensure that the benefits of a drug or biological product outweigh its risks. The FDA or comparable foreign regulatory authorities may also impose requirements for costly post- marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product, such as long- term observational studies on natural exposure. The FDA and other agencies, including, without limitation, the U. S. Department of Justice, and comparable foreign regulatory authorities closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and ~~57~~ comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding off- label use and if we, or our collaborators, market any of our product candidates for which we, or they, receive regulatory approval for treatment other than their approved indications, we, or they, may be subject to warnings or enforcement action for off- label marketing. Violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws. Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed. We sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory, and other product development objectives or milestones for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of regulatory approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including: • our available capital resources or capital constraints we experience; • our **ability to pursue Accelerated Approval or any other actionable regulatory pathway for our product candidates; • our** receipt of approvals, if any, by the FDA and other comparable foreign regulatory authorities and the timing thereof; • the rate of progress, costs and results of our clinical trials and research and development activities, including the extent

of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria; • other actions, decisions or rules issued by regulators; • our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates; • the efforts of our collaborators with respect to the commercialization of our products; and • the securing of, costs related to, and timing issues associated with, product manufacturing, as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, the trading price of the ADSs or ordinary shares may decline. ~~58~~ Access to raw materials and products necessary for the conduct of clinical trials, for commercialization, if approved, and manufacturing of our product candidates and product, if any, is not guaranteed. We are dependent on third parties for the supply of various materials, chemical or biological products that are necessary to produce Viaskin patches for our clinical trials, and will need to depend on third parties to produce patches for our commercial supply, if Viaskin Peanut is approved. The supply of these materials could be reduced or interrupted at any time, including, without limitation, as a result of impacts due to pandemics, epidemics or other global health crises, natural disasters, new laws or regulations applicable to us or our suppliers, or other unfavorable global economic conditions, including as a result of the ongoing conflict between Russia- Ukraine, ~~Iracl~~ **Israel** - Hamas and other global political or military conflicts. In such case, we may not be able to find other suppliers of acceptable materials in appropriate quantities at an acceptable cost. If key suppliers or manufacturers are lost or the supply of materials is diminished or discontinued, we may not be able to continue to develop, manufacture and market our product candidates or products, if any, in a timely and competitive manner. In addition, these materials are subject to stringent manufacturing processes and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials could adversely affect our ability to complete trials and commercialize our products, if any, in a cost- effective and timely manner. To prevent such situations, we intend to diversify our supply sources by identifying a second source of supply for critical raw materials and materials, such as natural protein. If we encounter difficulties in the supply of these materials, chemicals or biological products, if we were not able to maintain our supply agreements or establish new agreements to develop and manufacture our products in the future, our business, prospects, financial condition, results and development could be significantly affected. Relying on third- party manufacturers may result in delays in our clinical development or commercialization efforts. Developing and commercializing new medicines entails significant risks and expenses. Our clinical trials may be delayed if third- party manufacturers are unable to assure a sufficient quantity of the drug product to meet our study needs. Currently, we have only one manufacturer, Sanofi S. A., or Sanofi, of the active pharmaceutical ingredients, or API, used in our Viaskin product candidates, including Viaskin Peanut, such as peanut protein extract and unmodified allergen milk extract. In February 2020, Sanofi announced that it plans to create a new company dedicated to the production and marketing to third parties of API. Subsequently, Sanofi consolidated its API commercial and development activities conducted in six of its European API production sites. While those API sites do not include the site in which the API used in our Viaskin product candidates is produced, there can be no assurances that this transition will not adversely impact our supply of API from Sanofi. If Sanofi does not continue to manufacture the API as required by us in a timely manner, we may not be able to find a substitute manufacturer on a timely basis and our commercialization efforts and clinical trials may be delayed. Further, Sanofi' s strategic alliance partner, Regeneron, entered into a clinical collaboration with Aimmune Therapeutics, to evaluate treatment with Palforzia in combination with Dupilumab in peanut allergic patients. Regeneron commenced a Phase 2 clinical trial in October 2018 under this collaboration. This potential competitive dynamic may make Sanofi less inclined to continue or renew their manufacturing arrangement with us on commercially reasonable terms or at all and, notwithstanding contractual protections, Sanofi may be able to utilize knowledge gained through their relationship with us in furtherance of their development of competitive therapies. We also expect to rely on Sanofi and on FAREVA for the manufacturing of the patch and on other third- party manufacturers for the manufacturing of commercial supply of Viaskin Peanut, if approved, and any other product for which we obtain regulatory approval. Sanofi may not be able to effectively scale its manufacturing capacity of our API to meet our commercialization needs and we may be unable to establish any agreements with other third- party manufacturers or to do so on acceptable terms. Even if Sanofi is able to meet our commercialization needs or if we are able to establish agreements with other third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • reliance on the third party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third party; ~~59~~ • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or non- renewal of the agreement by the third party at a time that is costly or inconvenient for us. Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of products with which we contract are required to operate in accordance with FDA- mandated current good manufacturing practices, or cGMPs, or comparable GMP requirements in foreign countries. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch or availability of products based on our product candidates into the market. Moreover, the constituent parts of a combination product retain their regulatory status (as a biologic or medical device, for example) and, as such, we or our contract manufacturers may be subject to additional requirements in the Quality System Regulation, or QSR, or comparable quality management systems in foreign countries, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA or other comparable foreign regulatory authorities, to monitor and ensure compliance with cGMP. Despite our efforts to audit and verify regulatory compliance, one or more of our third- party manufacturing vendors may be found on regulatory inspection by the FDA or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. Failure by third- party manufacturers to comply with applicable regulations could

result in sanctions being imposed on us, including shutdown of the third- party vendor, fines, injunctions, civil penalties, revocation or suspension of regulatory approval for any products granted pre- market approvals, invalidation of drug product lots or processes, seizures or recalls of products, operating restrictions, and criminal prosecutions. Our current and anticipated future dependence upon others for the manufacture of our product candidates or products, if approved, may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis. Our Viaskin product candidates may not be able to be manufactured profitably on a large enough scale to support commercialization. To date, our Viaskin product candidates have only been manufactured at a scale which is adequate to supply our research activities and clinical trials. There can be no assurance that the procedures currently used to manufacture our product candidates will work at a scale which is adequate for commercial needs and we may encounter difficulties in the production of Viaskin patches due to our or our partners' manufacturing capabilities. For example, in large- scale use, there is a possibility that our electrospray manufacturing tool, ES GEN4. 0, may have issues related to maintenance of production quality, protein stability, and allergenicity. Additionally, during production, the containment of the electrospray function and the use of the allergen in liquid form keep the environment from being contaminated by the allergens. However, if there is a malfunction in the handling or storage phases or during the production phases, allergens could be released into the atmosphere and sensitize anyone present in the environment. We have not built commercial- scale manufacturing facilities, and we have limited manufacturing experience with Viaskin patches. Additionally, while the production process was developed in strict compliance with current regulations, due to the originality of the product, we cannot predict if European or U. S. regulatory authorities will make new regulations applicable to our production process, or if we will have any future disagreements with such regulatory authorities regarding our interpretation of the regulatory requirements. We rely on a single supplier to produce, or contract for the production of, active ingredients and we rely on a single manufacturer to produce patches for our clinical trials and for our commercial supplies of any future ~~60~~ approved products. Even if we were to obtain access to quantities of active ingredients sufficient to allow us otherwise to expand our Viaskin manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all. In the event our Viaskin product candidates cannot be manufactured in sufficient quantities for commercialization, our future prospects could be significantly impacted and our financial prospects would be materially harmed. We, or the third parties upon whom we depend, may be adversely affected by earthquakes, other natural disasters or outbreaks of contagious diseases and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Earthquakes, other natural disasters or an outbreak of a contagious disease ~~, such as COVID- 19,~~ could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our facilities or infrastructure, that damaged critical infrastructure, such as the manufacturing facilities of our third- party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. We rely, and will rely in the future, on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates. We rely, and will rely in the future, on medical institutions, clinical investigators, CROs, contract laboratories and collaborators to perform data collection and analysis and others to carry out our clinical trials. Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if: • the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines; • we replace a third party; or • the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons. Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs. Even if collaborators with which we contract in the future successfully complete clinical trials of our product candidates, those candidates may not be commercialized successfully for other reasons. Even if we contract with collaborators that successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including ~~:~~ • failing to receive regulatory approval to market them as drugs; • being subject to proprietary rights held by others; • failing to obtain approval from regulatory authorities on the manufacturing of our products; • being difficult or expensive to manufacture on a commercial scale; ~~61~~ • having adverse side effects that make their use less desirable; • failing to compete effectively with products or treatments commercialized by competitors; or • failing to show long- term risk / benefit ratio of our products. Currently, we do not have commercial- ready marketing and sales infrastructure. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues. We currently have a limited commercial infrastructure. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non- technical capabilities or make arrangements with third parties to perform these services. For example, we are planning to hire sales representatives for the marketing of Viaskin Peanut in the United States, if approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This

may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include: • our inability to recruit, hire, retain and incentivize adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products; • the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with establishing an independent sales and marketing organization. If we enter into arrangements with third parties to perform sales, marketing and distribution services for the commercialization of Viaskin Peanut in the United States or the European Union, if approved, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market Viaskin Peanut or any of our other product candidates or may be unable to do so when needed or on terms that are favorable to us. We likely will have more limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively, or they may fail to comply with promotional requirements for prescription products that could render our products misbranded in violation of government regulations and thus potentially subject to enforcement. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing Viaskin Peanut or any of our other product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing Viaskin Peanut or any of our other product candidates, either on our own or through collaborations with one or more third parties, our business, results of operations, financial condition and prospects will be materially and adversely affected. ~~62~~ Our product candidates are regulated as biological products, or biologics, which may subject them to competition sooner than anticipated. The Biologics Price Competition and Innovation Act, or BPCIA, established an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA- licensed biological reference product. " Biosimilarity " means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. To meet the higher standard of " interchangeability, " an applicant must provide sufficient information to show biosimilarity and demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administrated more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Under the BPCIA, an application for a biosimilar or interchangeable product cannot be approved by the FDA until 12 years after the reference product was first licensed, and the FDA will not even accept an application for review until four years after the date of first licensure. The law is evolving, complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty and could have a material adverse effect on the future commercial prospects for our biological products. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, potentially creating the opportunity for biosimilar or interchangeable competition sooner than anticipated. **In** ~~Moreover,~~ the **EU** ~~process by which an interchangeable product~~ , **following grant** ~~once approved, will be substituted for any one~~ of ~~our reference products in~~ a ~~way that is similar to traditional generic substitution for non- biological products (i. e., drugs) is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing and subject to interpretation. The European Union provides opportunities for data and market exclusivity~~ related ~~to marketing authorizations. Upon receiving a~~ marketing authorization, innovative medicinal products ~~are~~ generally **benefit from** ~~entitled to receive~~ eight years of data exclusivity and 10 years of market exclusivity ~~, which run in parallel~~ . Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator' s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product ~~,~~ **.** ~~after~~ **After** ~~which a generic~~ **this period, an application** ~~or~~ **for** ~~biosimilar~~ marketing authorization ~~application can~~ **for a generic or biosimilar product may** be submitted, and the innovator' s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the European Union until 10 years have elapsed from the initial marketing authorization of the reference product in the European Union. The overall ten- year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years **following authorization** of ~~those~~ -- **the** ~~ten years~~ **reference product** , the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. ~~However, there~~ **There** is **, however,** no guarantee that a product will be considered by the European Union' s regulatory authorities to be a new chemical / biological entity, and products may not qualify for data exclusivity. In the European Union, there is **also** a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of ~~an~~ **a related** application for Marketing Authorization. Guidelines from the EMA detail the type ~~of~~ **and** quantity of supplementary data to be provided for different types of biological product ~~. 63 We also believe that our product candidates in the European Union should benefit from data and market exclusivity. As with the U. S., however, if competitors obtain marketing authorization for their biosimilar products, our products may become subject to competition from these biosimilars, with the attendant competitive pressure and consequences~~ . Even if any of our product candidates are commercialized, they may not be accepted by physicians, patients, or the medical community in general. Even if we, or our collaborators, are able to commercialize our product candidates, the products may become subject to market conditions that could harm our business.

Even if the medical community accepts a product as safe and efficacious for its indicated use, prescribers may choose to restrict the use of the product if we are, or any collaborator is, unable to demonstrate that, based on experience, clinical data, side- effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives regulatory approval, which will depend on a number of factors, including, but not limited to: • the demonstration of the clinical efficacy and safety of the product; • the approved labeling for the product and any required warnings; • the advantages and disadvantages of the product compared to alternative treatments; • our and any collaborator' s ability to educate the medical community about the safety and effectiveness of the product; • the coverage and reimbursement policies of government and commercial third- party payors pertaining to the product; • the market price of our product relative to competing treatments; and • our ability to effectively implement a scientific publication strategy. We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us. The biopharmaceuticals industry is highly competitive. Numerous biopharmaceutical and biotechnology companies, universities and other research entities are actively involved in the discovery, development and commercialization of therapeutic options to treat allergies, making it a highly competitive field. We have competitors in several jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Although we believe we are currently in a unique position with respect to the testing and treatment of food allergies in children, established competitors may invest heavily to quickly discover and develop novel compounds that could make any of our product candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to any of our product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. In the case of food allergies, we are aware of several food allergy academic studies and pharmaceutical developmental efforts connected with such studies that are currently being conducted in major medical centers and hospitals worldwide. These studies are evaluating forms of allergen desensitization treatments such as oral (OIT), sublingual (SLIT), subcutaneous (SCIT), or oral mucosal (OMIT), ~~and~~ cutaneous (CIT **), and intranasal (INT**) immunotherapy, or products using synthetic allergens, denatured allergens, small molecule inhibitors, or combinations of medicines or methods, or medicines using traditional methods such as Chinese herbs. ~~64~~ Studies combining other methods of allergen immunotherapy, such as OIT, with monoclonal antibodies (anti- IgE and anti- IL- 4Rα) as adjunct therapy are being conducted currently. These types of co- administrations may significantly improve the safety of specific allergen immunotherapies administered orally or subcutaneously. Monoclonal antibodies, used alone as monotherapy or in combination with allergen immunotherapy, may become significant competitors to our products. ~~On~~ **In** February ~~16~~ 2024, the FDA approved Xolair ® (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE- mediated food allergy. There is one treatment that is specific for peanut allergy **in children 1 to 17 years of age** , a proprietary form of OIT which was approved by the FDA and the European Commission: Palforzia, formulation of peanut flour developed by Aimmune Therapeutics, Inc., or Aimmune. Nestlé S. A. acquired Aimmune in October 2020, and divested the Palforzia business to Stallergenes Greer in September 2023. Government restrictions on pricing and reimbursement, as well as other healthcare payor cost- containment initiatives, may negatively impact our ability to generate revenues if we obtain regulatory approval to market a product. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may adversely affect one or more of the following: • our ability or our collaborators' ability to set a price we believe is fair for our products, if approved; • our ability or our collaborators' ability to obtain and maintain market acceptance by the medical community and patients; • our ability to generate revenues and achieve profitability; and • the availability of capital. Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third- party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution. Third- party payors are increasingly reducing reimbursements for medical products, drugs and services. **Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.** In addition, the U. S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Limited third- party reimbursement for our product candidates or a decision by a third- party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Various provisions of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, were designed to impact the provision of, or payment for, health care in the United States, including expanded Medicaid eligibility, subsidized insurance premiums, provided incentives for businesses to provide health care benefits, prohibited denials of coverage due to pre- existing conditions, established health insurance exchanges, and provided additional support for medical research. With regard to biopharmaceutical products, among other

things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. However, there have been **amendments to and** executive, judicial and Congressional ~~65~~ challenges to certain aspects of the ACA. For example, on ~~June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. On~~ August 16, 2022, ~~President Biden signed~~ the Inflation Reduction Act of 2022, or IRA, **was signed** into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the ~~Biden~~ **second Trump** administration will impact the ACA or operations. Following ACA, both the Budget Control Act of 2011 ~~and the American Taxpayer Relief Act of 2012, or the ATRA, include~~ **includes** , among other things, mandatory reductions in Medicare payments to certain providers. Additionally, in the United States, there have been several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, ~~in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to the Biden administration' s executive order, on September 9, 2021, the U. S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition,~~ the IRA, among other things, (i) directs HHS to negotiate the price of certain high- expenditure, single- ~~source drugs and biologics~~ **sourcebiologics that have been on the market for at least 11 years** covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated " maximum fair price " for such drugs and biologics under the law, **or the " Medicare Drug Price Negotiation Program ",** and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. These provisions **began to** take effect progressively starting in fiscal year 2023. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon prices** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** program is currently subject to legal ~~challenge~~ **challenges** . ~~It is currently unclear how the IRA~~ **On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products** will **become subject** ~~be implemented but is likely~~ to ~~have a significant impact on the pharmaceutical industry. In response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three -- the Medicare Drug new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price~~ **Price Negotiation Program** ~~of prescription drugs through the use of march- in rights under the Bayh- Dole Act~~ . On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additional **health** ~~legislative proposals to~~ reform **measures may continue and affect our business in unknown ways, particularly given the recent change in administration. The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services, or CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include, for example, directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation, or CMMI, to consider new payment and** healthcare **models to limit drug spending and eliminating the Biden administration' s executive order that directed HHS to establishing** ~~and~~ **an** ~~government insurance programs~~ **AI task force and developing a strategic plan** , ~~along with the trend toward managed~~ **and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and** ~~healthcare --~~ **health plans. Additionally** ~~in the United States~~ , **in its June 2024 decision in Loper Bright Enterprises v. Raimondo, or Loper Bright, the U. S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision** could ~~influence~~ **result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including** ~~the~~ **those** ~~purchase of medicines~~ **issued by the FDA. Congress may introduce** and ~~reduce demand and~~ **ultimately pass health care related legislation that could impact the drug approval** ~~prices~~ **process** ~~for our products, if approved~~ **and make changes to the Medicare Drug Price Negotiation Program created under the IRA** . 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. ~~66~~ In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for a medicinal product **, it may refuse to reimburse a product at the price set by the manufacturer** or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. ~~We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost- containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down.~~ Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. **This** Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No **.** 2021 / 2282 on Health Technology Assessment, amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force ~~in on~~ January **12,** ~~2022 and will apply as of January~~ 2025 **and has a phased implementation** , is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation ~~foresees a three- year transitional period and will permit~~ **permits** EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States ~~will~~ continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down ~~; particularly due to the financial strain that the COVID- 19 pandemic placed on national healthcare systems of the EU Member States~~ . These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third- party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as " reference prices " to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures ~~67~~ of the United States and generally tend to have significantly lower prices. We believe that pricing pressures at the federal and state levels in the United States, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators. Guidelines and recommendations published by various organizations may impact the use or reimbursement of Viaskin Peanut, if approved. Government authorities promulgate regulations and guidelines that may be directly applicable to us and any approved products. However, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payors, as well as patient communities. Recommendations by government authorities or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review, or ICER, which publish their findings and offer recommendations relating to the products' reimbursement by government and private payors. In July 2019, ICER published its final report assessing the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin Peanut and a competitor product candidate. The results of this or any future ICER report or any similar recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use or reimbursement of Viaskin Peanut, if approved, could have a material adverse effect on our results of operations and financial condition. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of Viaskin Peanut, if approved, could adversely affect the market price of our securities. Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label,

or result in significant negative consequences following regulatory approval, if any. Our product candidates are being developed to address the needs of allergic patients, for some of whom they can have a profound and life- threatening adverse reaction if exposed to even minute amounts of an allergen. Accordingly, safety is of paramount importance in developing these product candidates. To date, more than twelve clinical trials of Viaskin Peanut and Viaskin Milk product candidates have been conducted both outside and inside of the United States in over ~~1~~ **2** , 000 human subjects to evaluate the safety and efficacy of these product candidates for the treatment of peanut allergies and milk allergies, respectively. Adverse events observed in these clinical trials have primarily involved general disorders such skin and subcutaneous tissue, immune system and administration site conditions, such as erythema, pruritus, edema and urticaria. However, in clinical trials to date, one case of mild to moderate anaphylaxis has been reported, and it is possible that anaphylaxis or other systemic reactions may occur in the future. It is worth noting that, as a desensitization patch bringing the allergen into contact with the skin, reactions, which are a source of itching and discomfort for subjects, are common. This reaction is typically temporary in duration and fades after a few weeks of use. In addition, during daily administration of the patches during treatments, depending on the severity of the allergies and subject response to treatment, precautionary measures are necessary when handling the patches after use due to risk of contamination. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, halt or terminate clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Further, if our Viaskin patch product candidates receive regulatory approval and we or others identify undesirable side effects caused by the products (or any ~~68~~ other similar products) after approval, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approval of the products; • regulatory authorities may require the addition of labeling statements, such as a " boxed " warning or a contraindication; • we may be required to change the way the products are distributed or administered, conduct additional clinical trials or change the labeling of the products; • we may decide to remove the products from the marketplace; • we could be sued and held liable for injury caused to individuals exposed to or taking our products; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected products and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues. Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability will depend, in part, on our ability to commercialize product candidates based on our Viaskin technology platform in multiple markets, including but not limited to those within the United States and Europe. If we commercialize product candidates based on our Viaskin technology platform in foreign markets, we would be subject to additional risks and uncertainties, including: • the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • import or export licensing requirements; • longer accounts receivable collection times; • longer lead times for shipping; • language barriers for technical training; • reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics; • foreign currency exchange rate fluctuations; • patients' ability to obtain reimbursement for Viaskin patch products in foreign markets; and • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. Foreign sales of Viaskin patch products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. ~~The United Kingdom' s withdrawal from the EU may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our common shares. Following Brexit, the UK and the EU signed a EU- UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and entered into force on May 1, 2021. This agreement provides details on how some aspects of the UK and EU' s relationship will operate going forwards however there 69 are still uncertainties. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a " third country, " a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland continues to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re- released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU Member States no longer encompasses Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities is required to place medicinal products on the market in Great Britain. Northern Ireland continues, however, to be covered by the marketing authorizations granted by the European Commission. On February 27, 2023, the UK Government and the European Commission reached a political agreement on the so- called " Windsor Framework ". The Framework is intended to revise the Northern Ireland Protocol to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK- only regulatory environment under the~~

authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in stages, with new arrangements relating to the supply of medicinal products into Northern Ireland anticipated to take effect in 2025. A significant proportion of the regulatory framework in the UK applicable to medicinal products is currently derived from EU Directives and Regulations. The potential for UK legislation to diverge from EU legislation following Brexit could materially impact the regulatory regime with respect to the development, manufacture, import, approval, and commercialization of our product candidates in the UK or the EU. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK or the EU for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU. 70 We are subject to healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, integrity obligations, exclusion from government healthcare programs, individual imprisonment, contractual damages, reputational harm and diminished profits and future earnings, among other consequences. Healthcare providers and others will play a primary role in the recommendation and prescription of Viaskin patch products, if approved. Our arrangements with such persons and third- party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute Viaskin patch products, if we obtain regulatory approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include but are not limited to the following: • The federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for or the purchase, lease, order or recommendation of any item, good, facility or service for which payment may be made under federal healthcare programs such as Medicare and Medicaid. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. The intent standard under the federal Anti- Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. • The federal civil and criminal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. • The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose certain requirements on covered entities and their business associates, and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. • The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website. 71 • Analogous state, local or foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state and local marketing and / or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require licensure or registration of pharmaceutical sales representatives; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA. Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by

strict laws, such as national anti- bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our current and / or future business activities could be subject to challenge under one or more of these laws. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could substantially disrupt our operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs. Changes in regulatory requirements, or guidance from the FDA or comparable foreign regulatory authorities or unanticipated events during our clinical trials of Viaskin products may occur, which may result in changes to clinical trial protocols or additional clinical trial requirements, which could result in increased costs to us and could delay our development timeline. Changes in regulatory requirements, or guidance from the FDA or comparable foreign regulatory authorities or unanticipated events during our clinical trials may force us to amend clinical trial protocols or the FDA or certain foreign regulatory authorities may impose additional clinical trial requirements. Discussions with regulatory authorities have caused us to adjust certain trial protocols. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs or competent foreign regulatory authorities, for review and approval, as applicable, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for the Viaskin patch product candidates, or any other product candidates, may be harmed and our ability to generate product revenue will be delayed. In addition, the policies of the FDA, the competent authorities of the EU Member States, the EMA, the European Commission and other comparable regulatory authorities responsible for clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ~~, or~~ **(“** CTR **”)** , which was adopted in April 2014 and repeals the EU Clinical Trials Directive **(“ CTD ”)** , became applicable on January 31, 2022. The CTR allows sponsors to make a single ~~72~~ submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EU Member States concerned, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State' s decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR ~~foresees~~ **foresaw** a three- year transition period **that ended** ~~. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made~~ on ~~the basis of the Clinical Trials Directive before~~ January 31, ~~2023~~ **2025** . ~~By that~~ **Since this** date, all **new or** ongoing trials **are** ~~has become~~ subject to the provisions of the CTR ~~. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025~~ . Compliance with the CTR requirements by us and our third ~~-~~ party service providers, such as CROs, may impact our ~~developments~~ - **development** plans **In light of the entry into application of the CTR on January 31, 2022, we may be required to transition clinical trials for which we have obtained regulatory approvals in accordance with the CTD to the regulatory framework of the CTR. Transition of clinical trials governed by the CTD to the CTR was required for clinical trials which had at least one site active in the EU on January 30, 2025. A transitioning application had to be submitted to the competent authorities of EU Member States through the Clinical Trials Information Systems and related regulatory approval obtained to continue the clinical trial past January 30, 2025. This required financial, technical and human resources** . It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency, or MHRA, launched an eight- week consultation on reframing the UK legislation for clinical trials. The UK Government published its response to the consultation on March 21, 2023 confirming that it would bring forward changes to the legislation **and such changes were laid in parliament on December 12, 2024** . These resulting legislative amendments will ~~determine how closely~~ **, if implemented in their current form, bring** the UK ~~regulations will align~~ **into closer alignment** with the CTR. Failure of the UK to closely align its regulations with the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries and / or make it harder to seek a marketing authorization for our product candidates on the basis of clinical trials conducted in the UK. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. The FDA and other comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off- label uses. If we are found to have improperly promoted off- label uses, we may become subject to significant liability. The FDA and other comparable foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as Viaskin patch products, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other comparable foreign regulatory authorities, as reflected in the product' s

approved labeling. If we receive regulatory approval for Viaskin patch products as a treatment for a particular allergy, physicians, in their independent professional medical judgment, may nevertheless prescribe Viaskin patch products to their patients in a manner that is inconsistent with the approved label. Additionally, it is permissible to share in certain circumstances and in accordance with applicable FDA, and comparable regulatory authorities', guidance and regulations truthful and non-misleading information that is consistent with, but not contained in, the product' s approved labeling. If we are found to have promoted off- label uses or promoted our product before approval, we may become subject to significant liability under the FDCA and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA and other U. S. government agencies has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the marketing of Viaskin patch products, if approved, by restricting off- label promotion, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Similar limitations and penalties are provided in the EU both at EU level and at national level in individual EU Member States. ~~73~~ Our product development programs may require substantial financial resources and may ultimately be unsuccessful. The success of our business depends primarily upon our ability to identify, develop and commercialize products to treat food allergies. In addition to Viaskin Peanut, we may pursue development of our other development programs, including Viaskin Milk. None of our other product candidates and potential product candidates has commenced any clinical trials since we scaled down our research and clinical development efforts in 2020 and 2021 to focus on Viaskin Peanut. There are a number of FDA or foreign requirements that we must satisfy before we can commence clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. We may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or comparable foreign regulatory authorities. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. If we do not secure collaborations with strategic partners to test, commercialize and manufacture certain product candidates outside of food allergies, we may not be able to successfully develop products and generate meaningful revenues. A key aspect of our current strategy is to selectively enter into collaborations with third parties to conduct clinical testing. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We currently have multiple collaboration agreements in effect, including collaborations for the development of applications in the field of respiratory allergies or autoimmune disease, as well as other therapeutic domains, such as vaccines. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates. Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize products using our product candidates. Collaborations involving our product candidates pose a number of risks, including the following: • collaborators may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus; • collaborators may believe our intellectual property is not valid, is not infringed by potential competitors or is unenforceable or the product candidate infringes on the intellectual property rights of others; • collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues; • collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement; • collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or • collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing another party' s product candidate. ~~74~~ Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. Collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure new collaborations that achieve the collaborator' s objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues. Intellectual Property Risks Related to Our Business Our ability to compete may decline if we do not adequately protect our proprietary rights. Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates for the treatment of common food or other allergies, as well as successfully defending these rights against third- party challenges. We will only be able to protect our product candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain **and / or maintain** patent protection for our product candidates is uncertain due to a number of factors, including: • we may not have been the first to make the inventions covered by pending patent applications or issued patents; • we may not have been the first to file patent applications for our product candidates or the compositions we developed or for their uses; • others may independently develop identical, similar or alternative products or compositions and uses thereof; • our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability; • any or all of our pending patent applications may not result in issued patents; • we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity; • any patents issued to us may not protect, encompass, or embody commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties; • our compositions and methods may not be patentable; • others may design around our patent claims to produce competitive products which fall outside of the scope of our

patents; **• our issued patents could potentially be found to be unenforceable;** or • others may identify prior art or other bases which could invalidate our patents. Even if we have or obtain patents covering our product candidates or compositions, we may still be barred from making, using and selling our product candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to our compositions or products. There are many issued U. S. and foreign patents relating to biological or chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U. S. and foreign issued patents and pending patent applications owned by others exist in the allergy treatment field in which we are developing products. Any or all of these could materially affect our ability to develop our product candidates or sell our products if approved. Because patent applications can take many years to issue as patents, and because there can be procedures to keep some applications secret, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us. ~~75~~ Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and / or applications due in several stages over the lifetime of patents and / or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process and after a patent grants. There may also be significant expenses associated with enforcing and / or defending various patents in a patent portfolio **or with challenging patents that could unfairly exclude our products and product candidates from being marketed once approved** . We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction (perhaps irrevocably). If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. Legal actions to enforce and / or defend our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents and / or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations. If we develop a reputation of failing to attempt to protect or to enforce our intellectual property rights, our competitive position could suffer, which could harm results of operation. Biopharmaceutical patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position. The patent positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biopharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the 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; U. S. patents may be subject to reexamination proceedings, post- grant review and / or inter partes review in the USPTO (collectively, " post-grant proceedings "). Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, 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, the United States Court of Appeals for the Federal Circuit, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the ~~76~~ standards of patentability and any such changes could have a negative impact on our business. For example, recently the federal courts and the United States Supreme Court have issued (and may issue additional) ~~rules~~ **rulings** generally related to standards for upholding the validity of biological and chemical " genus " claims. Any rulings that make it more difficult to uphold the validity of biological or chemical " genus " claims could potentially negatively impact our patent portfolio and negatively impact our business. In addition, the Leahy- Smith America Invents Act, 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 and prosecuted during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed (and continues to develop) new and untested, or relatively lightly tested, regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first- to- file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain

patents, and if obtained, to enforce or defend them. Accordingly, it is **still** not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business. In addition, over the past few years, bills in the U. S. Congress have ~~bene-~~ **been** proposed that, if passed, would make changes to the America Invents Act. For example, bills have been introduced that would reduce the discretion of the Patent Trial and Appeal Board (PTAB) to deny some or all post- grant proceedings. In addition, bills, rules and / or regulations have been introduced that would provide the director of the U. S. P. T. O more authority to set aside PTAB decisions. If these bills are eventually passed by the U. S. Congress and become law, they could impact our ability to enforce / defend patents. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We do, and expect to, enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party' s relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or ~~77~~ misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting, defending, and maintaining patents, and defending other intellectual property rights such as trade secrets, on our product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are generally based on the priority dates of each of our patent applications. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing in these or other jurisdictions. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties under certain circumstances. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country 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 ~~78~~ arising from our collaborations. These agreements provide that we may have to negotiate certain

commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third- party collaborator' s materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator' s ~~samples~~ **materials** , we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We employ individuals who were previously employed at universities or other biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business. There is significant litigation in the biopharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our product candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents or other intellectual property rights, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third- party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and the price of the ADSs. Any legal action against us or our collaborators could lead to: • payment of damages, potentially treble damages, if we are found to have willfully infringed a party' s patent rights; ~~79~~ • 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 ~~80~~ and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for unenforceability assertions include allegations of lack of candor or good faith in dealing with USPTO, that someone connected with prosecution of the patent withheld relevant and / or materials information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims **regarding invalidity and / or unenforceability** before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review, inter partes review, and equivalent proceedings in foreign jurisdictions, e. g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover, encompass, or protect our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. If a party were to prevail on a legal assertion of unenforceability, such a holding could also affect other related patents. Such a loss of patent protection would have a material adverse impact on our business. Risks Related to Our Organization, Structure and Operations We depend on key personnel and attracting qualified management personnel and our business could be harmed if we lose key personnel and cannot attract new personnel. Our success depends to a significant degree upon the technical and management skills of our officers and key personnel. The loss of the services of any of these individuals would likely have an adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management. Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our key executives could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition, and results of operations. Our employees may engage in misconduct or other improper activities, including violating applicable regulatory standards and requirements or engaging in insider trading, which could significantly harm our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to: comply with the regulations of the FDA and applicable foreign regulatory authorities, provide accurate information to the FDA and applicable foreign regulatory authorities, comply with fraud and abuse and other healthcare laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of, including trading on, ~~81~~ information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may be ineffective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates. The risk that we may be sued on product liability claims is inherent in the development and commercialization of biopharmaceutical products. Side effects of, or manufacturing defects in, products that we develop could result in the deterioration of a patient' s condition, injury or even death. For example, product liability claims may be brought by subjects participating in our clinical trials as a result of unexpected side effects from our product candidates. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Criminal or civil proceedings might be filed against us by patients, regulatory authorities, other biopharmaceutical companies and any other third party using or marketing our products. These actions could include claims resulting from acts by our partners, licensees and subcontractors, over which we have little or no control. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and we may be forced to limit or forgo further commercialization of the affected products. We may incur significant costs from class action litigation. The market price for our ordinary shares or ADSs recently has and may continue to fluctuate for many reasons, including as a result of public announcements regarding the progress of our development and commercialization efforts or the development and commercialization efforts of our collaborators and / or competitors, the addition or departure of our key personnel, variations in our operating results and changes

in market valuations of pharmaceutical and biotechnology companies. When the market price of a security has been volatile as the market price for our ordinary shares and ADSs has been, holders of that security have occasionally brought securities class action litigation against the company that issued the security. For example, in December 2018, we announced that we voluntarily withdrew our BLA for Viaskin Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls, and our ADS price declined significantly as a result. Following this announcement, a class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey alleging that we and our former Chief Executive Officer, our current Chief Executive Officer, our former Deputy Chief Executive Officer, and our former Chief Business Officer violated certain federal securities laws, specifically under Sections 10 (b) and 20 (a) of the Exchange Act, and Rule 10b- 5 promulgated thereunder. The plaintiffs sought unspecified damages on behalf of a purported class of persons that purchased our securities between February 14, 2018 and August 4, 2020 and also held our securities on December 20, 2018 and / or March 16, 2020 and / or August 4, 2020. The complaint, as amended, was dismissed with prejudice on July 29, 2022, and the matter was resolved with finality thirty days thereafter. Whether or not a plaintiff' s claims are successful, this type of litigation is often expensive and diverts management' s attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations. We may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management' s attention and resources, which could cause serious harm to our business, operating ~~82~~ results and financial condition. We maintain liability insurance; however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial. We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial condition and operations. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. We currently carry product liability insurance coverage for our clinical trials. Although we maintain such insurance, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims by us or our partners, licensees or subcontractors, which could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully. Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our **Operating Income** ~~results of operations.~~ As a French technology company, we have benefited from certain tax advantages, including, for example, the French ~~research~~ **Research** ~~tax~~ **Tax** ~~credit~~ **Credit** (~~credit~~ **crédit** d' impôt recherche), or CIR. The CIR is a French tax credit aimed at stimulating research and development. Beginning in the fiscal year ending December 31, 2021, the Company recovered its Small and Medium- sized Enterprises, or SMEs, status under EU law, and became therefore eligible again for the immediate reimbursement of the Research Tax Credit. ~~During the fiscal year ending December 31, 2022, the Company received the reimbursement of the 2019, 2020 and 2021 fiscal year research tax credit for a total amount of $ 26. 1 million.~~ The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented $ **4. 1 million and $** 8. ~~9~~ **8** ~~millions~~ **million** ~~and $ 5. 7 millions~~, as of December 31, **2024 and** 2023 ~~and 2022~~ respectively. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR benefit. The French tax authorities may challenge our eligibility to, or our calculation of certain tax reductions and / or deductions in respect of our research and development activities and, should the French tax authorities be successful, we may be liable to additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the French Parliament decides to eliminate, or reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected. We may be exposed to significant foreign exchange risk. Exchange rate fluctuations may adversely affect the foreign currency value of our ADSs. We incur portions of our expenses, and may in the future derive revenues, in currencies other than the euro, in particular, the U. S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U. S. dollar could be expected to have a negative impact on our revenue and earnings growth as U. S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ADSs are quoted in U. S. dollars on the Nasdaq **Capital** ~~Global Select~~ Market and our ordinary shares are trading in euros on Euronext Paris. Our financial statements are prepared in euros. ~~83~~ Fluctuations in the exchange rate between euros and the U. S. dollar will affect, among other matters, the U. S. dollar value and the euro value of our ordinary shares and ADSs. We may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly. Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. For example, in production, the confinement of the electrospray function and the use of the allergen in liquid form make it possible to prevent the allergens from contaminating the environment. However, we cannot assure you that in case of malfunction during the handling, storage or production process, allergen would not be released into the atmosphere and sensitize the persons present

in the environment. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state, local or foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. An allegation of noncompliance by applicable regulatory authorities with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean- up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced. We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse business consequences. In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third- party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that govern the processing of personal data by us and on our behalf. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the California Consumer Privacy Act of 2018, or CCPA, imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $ 7, 500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the California Privacy Rights Act of 2020, CPRA, effective January 1, 2023, has expanded the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts. ~~84~~ Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union' s General Data Protection Regulation, or EU GDPR, and the United Kingdom' s GDPR, or UK GDPR, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to € 20 million ~~euros~~ or 4 % of the total annual global revenue of the preceding year, whichever is greater. Furthermore, companies may face private litigation related to processing of personal data brought by data subjects, classes of data subjects or consumer protection organizations authorized at law to represent their interests. Certain jurisdictions have enacted data localization laws and cross- border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the European Economic Area, or EEA, or in other foreign jurisdictions). Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States on a long- term basis. The EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States. The European Commission adopted an adequacy decision for the EU- US Data Privacy Framework, or DPF, on July 10, 2023, further to the Biden Administration' s Executive Order dated October 7, 2022 which provides that entities in the EEA may transfer personal data to entities in the United States that adhere and comply with the DPF without having to implement additional safeguards. However, the DPF is may not provide adequate protection given the previous successive invalidations of previously EU- US adequacy mechanisms and the periodic review of the DPF by the European Commission. The European Commission released a set of " Standard Contractual Clauses, " or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. These SCCs can be a valid mechanism to transfer personal data outside of the EEA. However, only entering into SCCs may not be sufficiency and additional compliance burdens are required, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at- issue personal data. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries, such as the United States, and certain countries outside Europe (e. g., Russia, China, Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we cannot transfer personal data from the EEA, the UK or other jurisdictions to the United States in a lawful manner, or if the costs for such lawful transfers of personal data are too high, we may face increased exposure to regulatory actions, substantial fines and penalties, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations; limiting our ability to collaborate with parties that are subject to such cross- border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense; or interrupting or adversely impacting

our operations. Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third- party processor to comply with applicable law, regulations, or contractual obligations including, providing appropriate notice to data subjects, obtaining necessary consents, or establishing a legal basis for the transfer and processing of the data by us, could result in ~~85~~ adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- related claims); additional reporting requirements and / or oversight; payment of damages; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; revision or restructuring of our operations; or loss of revenue or profits; and other adverse business consequences. If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences. In the ordinary course of our business, we and the third parties upon which we rely, may process proprietary, confidential, and sensitive data, including personal data (such as health- related data), intellectual property, and trade secrets (collectively, sensitive information). We may rely upon third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third- party providers of cloud- based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Cyberattacks, malicious internet- based activity, and online and offline fraud threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. These threats are prevalent and continue to increase. These threats come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists ", organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including, without limitation, nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber- attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, social- engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, flood and other similar threats. Severe ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our ~~86~~ operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Additionally, our workforce' s use of network connections, computers, and devices outside our premises or networks, including working remotely from home, while in transit, and in public locations, poses increased risks to our information technology systems and data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not previously identified while conducting due diligence acquired or integrated entities and it may be difficult to integrate companies into our information technology environment and security program. Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to sensitive information held by us or our information technology systems, or

those of the third parties upon whom we rely. A security incident or other interruption disrupt our ability (and that of third parties upon whom we rely) to conduct our business operations. We may expend significant resources or modify our business activities to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and sensitive information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities but we may not be able to detect and remediate all vulnerabilities because threats and techniques used to exploit the vulnerability change frequently, are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. ~~87~~ We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. At this stage, our strategy does not involve plans to acquire companies or technologies facilitating or enabling us to access to new medicines, new research projects or new geographical areas, or enabling us to express synergies with our existing operations. However, if our strategy changes or if such acquisitions were to become necessary in the future, we may not be able to identify appropriate targets or make acquisitions under satisfactory conditions, in particular, satisfactory price conditions. In addition, we may be unable to obtain the financing for these acquisitions under favorable conditions, and could be led to finance these acquisitions using cash that could be allocated to other purposes in the context of existing operations. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction, which could have a material adverse effect on our business, financial conditions, earnings and prospects. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We will need to develop and implement sales, marketing and distribution capabilities before we are able to bring any product candidate to market, and as a result, we may encounter difficulties in managing this development and expansion, which could disrupt our operations. As of December 31, ~~2023~~ **2024**, we had ~~104~~ **109** full- time employees. Before we can commercialize Viaskin Peanut, if approved, and any of our other product candidates in North America, we will need to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing any such development activities we may pursue. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may

result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Any physical expansion of our operations may lead to significant ~~88~~ costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company. Risks Related to Ownership of Our Ordinary Shares and ADSs The market price for our ordinary shares and ADSs may be volatile or may decline regardless of our operating performance. The trading price of our ADSs and ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of our securities depends on a number of factors, including those described in this " Risk Factors " section, many of which are beyond our control and may not be related to our operating performance. Our ADSs were sold in our initial public offering on Nasdaq in October 2014 at a **closing** price of $ 21. 64 per share, and the **closing** price per ADS has ranged from as low as $ 0. ~~70~~ **469** and as high as $ ~~2~~ **4** . ~~23~~ **250** during ~~2023~~ **2024** **(with the current ratio of five (5) ordinary shares to one (1) ADS)** . During this same period, our ordinary share prices have ranged from as low as € ~~1~~ **0** . ~~40~~ **510** to as high as € ~~4~~ **1** . ~~07~~ **857** . The market price of our securities may fluctuate significantly in response to numerous factors, many of which are beyond our control, including: • actual or anticipated fluctuations in our financial condition and operating results; • actual or anticipated changes in our growth rate relative to our competitors; • competition from existing products or new products that may emerge; • regulatory actions with respect to our products or our competitors' products, including the potential resubmission to the FDA of a BLA for Viaskin Peanut; • announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments; • failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; • issuance of new or updated research or reports by securities analysts; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs and / or ordinary shares; • additions or departures of key management or scientific personnel; • disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies; • changes in the structure of healthcare payment systems; • changes to coverage policies or reimbursement levels by commercial third- party payors and government payors and any announcements relating to coverage policies or reimbursement levels; • announcement or expectation of additional debt or equity financing efforts; • sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and • general economic and market conditions. These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating ~~89~~ performance, which may limit or prevent investors from readily selling their ADSs or ordinary shares and may otherwise negatively affect the liquidity of our ADSs and ordinary shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Share ownership is concentrated in the hands of our principal shareholders and management, who will continue to be able to exercise a direct or indirect controlling influence on us. As of December 31, ~~2023~~ **2024** , our executive officers, directors, current 5 % or greater shareholders and affiliated entities, including entities affiliated with Baker Bros. Advisors LP, entities affiliated with Braidwell, L. P., entities affiliated with VR Adviser, LLC, and entities affiliated with Bpifrance Participations S. A., together beneficially own approximately 47 % of our ordinary shares. As a result, these shareholders, acting together, will have significant influence over all matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate action might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and trading volume could decline. The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our ADSs or ordinary shares or publishes incorrect or unfavorable research about our business, the price of our ADSs and ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our ADSs or ordinary shares, demand for our ADSs and ordinary shares could decrease, which could cause the price of our ADSs or ordinary shares or trading volume to decline. If we are not able to comply with the applicable continued listing requirements or standards of Nasdaq, our ADSs could be delisted. Our ADSs are currently listed on The Nasdaq ~~Global~~ **Capital** Market. In order to maintain that listing, we must satisfy certain continued listing requirements and standards, including, among others, minimum stockholders' equity, minimum share price, director independence and independent committee requirements, and certain corporate governance requirements. There can be no assurances that we will be able to comply with the applicable listing standards. For instance, on ~~January 14, 2021, we received a notice from Nasdaq indicating that we did not meet Nasdaq' s quorum requirement under Listing Rule 5620 (c) (i), or the Nasdaq Quorum Requirement, because our bylaws do not require a quorum for shareholders' meetings of at least 33 1 / 3 % of the outstanding shares of our voting ordinary shares. While our ADSs are listed on Nasdaq, our ordinary shares are listed on Euronext Paris. Applicable French laws and regulations prohibit French listed companies from having a quorum requirement for shareholders' meetings that is higher than the minimums set by French law. The minimum quorum requirements under French law are lower than the Nasdaq Quorum Requirement. In April 2021 following our discussions with Nasdaq, Nasdaq modified the Nasdaq Quorum Requirement, such that Nasdaq will accept a quorum requirement of the home country of a non- U. S. company that is lower than that required by Nasdaq, provided the company fulfill certain requirements. In April 2021, in~~

~~accordance with the amended Nasdaq Quorum Requirement, we fulfilled such requirements, including filing with the SEC a Current Report on Form 8- K disclosing that we had submitted a letter from our independent French counsel to Nasdaq stating that the laws of France mandate a 90 lower quorum for shareholders' meetings than that required by the Nasdaq Quorum Requirement, and that we cannot obtain an exemption or waiver from such requirements. We also posted a statement regarding our reliance on the exception from the Nasdaq Quorum Requirement on our website. On April 26, 2021, Nasdaq notified us that we regained compliance with the Nasdaq Quorum Requirement. On~~ December 20, 2023, we received a letter from the Listing Qualifications Staff of Nasdaq notifying the us that for the last 30 consecutive business days, the bid price of our ADSs had closed below $ 1. 00 per share, the minimum closing bid price required by the continued listing requirements of Nasdaq Listing Rule 5550 (a) (2). **On May 31, 2024, the Company announced plans to change the ratio of its ADS to its ordinary shares (the " ADS Ratio "), nominal value € 0. 10 (ten cents) per share, from the current ADS Ratio of one (1) ADS to one- half (1 / 2) of one (1) ordinary share to a new ADS Ratio of one (1) ADS to one (1) ordinary share (the " ADS Ratio Change "). The ADS Ratio Change was effective on June 7, 2024.** In **addition** ~~accordance with Nasdaq Listing Rule 5810 (c) (3) (A)~~ , ~~we have~~ **to obtain an additional** 180 ~~calendar~~ days **period** ~~, or until June 17, 2024,~~ to regain compliance with the **NASDAQ** minimum bid price requirement ~~. To regain compliance~~ , the ~~closing bid price~~ **Company applied to transfer its securities from the NASDAQ Global Select Market to the NASDAQ Capital Market (the " NCM "). On June 18, 2024, the Company was notified by the Listing Qualifications Department that NASDAQ granted the Company' s request to transfer the listing** of ~~our~~ **its** ADSs ~~must be at least $ 1. 00 per share~~ **from the NASDAQ Global Select Market tier to the NCM tier, and that NASDAQ granted the Company' s request** for a **second** ~~minimum of 10 consecutive business days before the expiration of the~~ 180- day period ~~. To regain compliance~~ , ~~during the 180 day period the minimum bid price of our~~ **or until December 16, 2024, to** ~~ADSs must close at $ 1. 00 per share or more for a minimum of 10 consecutive business days. If we do not~~ regain compliance with the **$ 1. 00 bid price requirement. The Company' s ADSs were transferred to the NCM at the opening of business on June 20, 2024. On November 11, 2024, the Company announced plans to implement an additional ADS ratio change from the ratio of one (1) ADS to one (1) ordinary share to a ratio of one (1) ADS to five (5) ordinary shares. This ratio change was effect on November 29, 2024. On December 13, 2024, the Company received notice from** Nasdaq **confirming that** ~~Listing Rules prior to~~ the **Company regained** ~~expiration of the 180- day~~ compliance **with the minimum closing bid price criteria of the** ~~period, we may be eligible for additional time to regain compliance pursuant to~~ Nasdaq ~~Listing~~ **listing requirements** ~~Rule 5810 (c) (3) (A) (ii)~~ . Notwithstanding our ability to regain compliance with the Nasdaq Listing Rules, we may fail to satisfy one or more Nasdaq requirements for continued listing of our ADSs in the future. In the event that our ADSs are delisted from Nasdaq and are not eligible for quotation or listing on another market or exchange, trading of our ADSs could be conducted only in the over- the- counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our ADSs, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our ADSs to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange. Delisting would also likely have a negative effect on the price of our ADSs, would affect our ability to raise additional capital through the public or private sale of equity securities, and would impair your ability to sell or purchase our ADSs when you wish to do so. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional interest and fewer business development opportunities. In the event of a delisting, we may take actions to restore our compliance with Nasdaq' s listing requirements, but we can provide no assurance that any such action taken by us would allow our ADSs to become listed again, stabilize the market price or improve the liquidity of our ADSs, prevent our ADSs from dropping below Nasdaq minimum bid price requirement or prevent future non- compliance with Nasdaq' s listing requirements. We do not currently intend to pay dividends on our securities and, consequently, your ability to achieve a return on your investment, if any, will depend on appreciation in the price of the ADSs. In addition, French law may limit the amount of dividends we are able to distribute. We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs. Investors seeking cash dividends should not purchase the ADSs. Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our annual financial statements. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France. ~~91~~ 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, ~~2023~~ **2024** , ~~96~~ **102** , ~~431~~ **847** , ~~770~~ **501** ordinary shares were issued and outstanding. Sales of a substantial number of shares of our ordinary shares or ADSs in the public market, or the perception that these sales might occur, could depress the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our shares are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly. In June 2022, we completed a $ 194 million PIPE financing (the " June 2022 PIPE ") from the sale of (i) 32, 855, 669 Ordinary Shares, nominal value € 0. 10 per share at a price per Ordinary Share of € 3. 00

(corresponding to $ 3. 22 on the basis of an exchange rate of $ 1. 0739 = € 1. 00 published by the European Central Bank on June 8, 2022), and (ii) pre- funded warrants to purchase an aggregate of 28, 276, 331 Ordinary Shares (the " Warrant Shares ") at a pre- funded price per pre- funded warrant of € 2. 90 (corresponding to $ 3. 11), which equals the per share price of the Ordinary Shares less the exercise price of € 0. 10 per pre- funded warrant. Each pre- funded warrant has an exercise price of € 0. 10 per Warrant Share. Pursuant to a registration rights agreement (the " Registration Rights Agreement ") with the investors, the Company filed a registration statement with the SEC registering the resale of 59, 269, 629 ordinary shares issued in the June 2022 PIPE, including ordinary shares underlying the pre- funded warrants. The Company also filed a registration statement with the SEC registering the resale of 11, 593, 170 ordinary shares by Entities affiliated with Baker Bros. Advisors, issued in the June 2022 PIPE, including ordinary shares underlying the pre- funded warrants. As a result, subject to certain beneficial ownership limitations contained in the pre- funded warrants, these shares are freely tradable, without restriction, in the public market. In addition, the exercise of some or all of the pre- funded warrants will increase the number of our outstanding ordinary shares, which may dilute the ownership percentage or voting power of our shareholders. In addition, we have filed a registration statement with the SEC to register the ordinary shares that may be issued under our equity incentive plans. The ordinary shares subject to outstanding options under our equity incentive plans, ordinary shares reserved for future issuance under our equity incentive plans and ordinary shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our securities. The dual listing of our ordinary shares and our ADSs may adversely affect the liquidity and value of the ADSs. Our ADSs are traded on the Nasdaq **Capital** ~~Global Select~~ Market, and our ordinary shares are listed on Euronext Paris. The dual listing of our ordinary shares and our ADSs may dilute the liquidity of these securities in one or both markets and may adversely affect the maintenance of an active trading market for our ADSs in the United States. The price of our ADSs could also be adversely affected by trading in our ordinary shares on Euronext Paris, and vice versa. In addition, currency fluctuations as between the euro and U. S. dollar may have an adverse impact on the value of our ADSs. ~~92~~ Our by- laws and French corporate law contain provisions that may delay or discourage a takeover attempt. Provisions contained in our by- laws and the corporate laws of France, the country in which we are incorporated, could make it more difficult for a third- party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our by- laws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following: • under French law, a non- French resident as well as any French entity controlled by non- French residents may have to file a declaration for statistical purposes with the Banque de France, within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding € 15, 000, 000 that lead to the acquisition of at least 10 % of our share capital or voting rights or cross such 10 % threshold; • under French law, certain investments in a French company relating to certain strategic industries by individuals or entities not established in a Member State of the EU are subject to prior authorization of the Ministry of Economy; • the owner of 90 % of the share capital and voting rights of a public company listed on a regulated market in an EEA country, including from the main French Stock Exchange, has the right to force out minority shareholders following a tender offer made to all shareholders; • a merger (i. e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two- thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting; • under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder; • our shareholders have granted and may grant in the future our board of directors' broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares; • our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set- off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two- thirds majority vote) of our shareholders or on an individual basis by each shareholder; • our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors; • our board of directors can only be convened by our chairman or our managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one- third of the total number of directors; • our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board' s decisions; however, this mode of participation (by way of videoconference or teleconference) does not apply to the adoption of decisions taken for the closing of the accounts for the fiscal year, including the consolidated financial statements; • our shares are nominative or bearer, if the legislation so permits, according to the shareholder' s choice. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the ~~93~~ name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions; • approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause; • advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice; • our by- laws can be changed in accordance with applicable laws; • the crossing of certain thresholds has to be disclosed and can impose certain obligations; • transfers of shares shall comply with applicable insider trading rules and regulations and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and • pursuant to French law, the sections of

the by- laws relating to the number of directors and election and removal of a director from office may only be modified by a resolution adopted by at least a two thirds majority vote of our shareholders present, represented by a proxy or voting by mail at the meeting. You may not be able to exercise your right to vote the ordinary shares underlying your ADSs. Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who shall be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary shall distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders. You may instruct the depositary of your ADSs to vote the ordinary shares underlying your ADSs. If the depositary timely receives voting instructions from you, it will endeavor to vote the securities (in person or by proxy) represented by the ADSs in accordance with such voting instructions. If the depositary receives voting instructions which fail to specify the manner in which the depositary is to vote the deposited securities, you will be deemed to have instructed the depositary to vote in favor of all resolutions endorsed by our board of directors. Otherwise, you will not be able to exercise your right to vote, unless you withdraw the ordinary shares underlying the ADSs you hold. However, you may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for your instructions, the depositary, upon timely notice from us, will notify you of the upcoming vote and arrange to deliver our voting materials to you. We cannot guarantee you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your ordinary shares or to withdraw your ordinary shares so that you can vote them yourself. If the depositary does not receive timely voting instructions from you, it may give a proxy to a person designated by us to vote the ordinary shares underlying your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote, and there may be nothing you can do if the ordinary shares underlying your ADSs are not voted as you requested. Your right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to your holdings. According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis, transferable during a period starting two days prior to ~~94~~ the opening of the subscription period or, if that day is not a trading day, the preceding trading day; and ending two days prior to the closing of the subscription period or, of that day is not a trading day, the preceding trading day, unless they waive those rights at an extraordinary meeting of our shareholders (by a two- thirds majority vote) or individually by each shareholder. However, the ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights. According to French law, as of December 31, ~~2023~~ **2024** we have issued: ~~- 28~~ **• 22** , ~~276~~ **266** , 331 pre- funded warrants at a pre- funded price per pre- funded warrant of € 2. 90 (corresponding to $ 3. 11), Each pre- funded warrant bears an exercise price of € 0. 10 per Warrant Share; ~~-~~ **•** Restricted Stock Units (“ RSU ”), stock options plan (“ SO ”), and non- employee warrants (~~Bons~~ **bons** de ~~Souscription~~ **souscription** d’ ~~Actions~~ **actions** i. e. “ BSA ”) representing globally ~~9~~ **13** , ~~458~~ **823** , ~~901~~ **961** outstanding shares as of December 31, ~~2023~~ **2024** . The exercise of some or all pre- funded warrants, RSU, SO and non- employee warrants will increase the number of outstanding ordinary shares, which may dilute the ownership percentage or voting power of shareholders **by13. 4** ~~by 9, 8~~ % (without pre- funded warrants exercise, and ~~39~~ **35** , 1 % should all pre- funded warrants be exercised). You may be subject to limitations on the transfer of your ADSs and the withdrawal of the underlying ordinary shares. Your ADSs, which may be evidenced by ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of your ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to your right to cancel your ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of your ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders’ meeting or we are paying a dividend on our ordinary shares. In addition, you may not be able to cancel your ADSs and withdraw the underlying ordinary shares when you owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities. ~~95~~ The biotechnology industry has been included in the list of critical technologies subject to foreign investment control procedure in France, which may limit the ability to certain non- French investors to participate in this or any other offering of our securities. The completion of any investment (i) by (a) an individual of foreign nationality, (b) any individual of French nationality not domiciled in France

within the meaning of article 4B of the French General Tax Code (Code ~~Général~~ **général** des ~~Impôts~~ **impôts**), (c) any entity governed by foreign law, and (d) any entity governed by French law controlled by one or more of the entities referred to in (a) to (c), (ii) which would result in (a) the acquisition of control — within the meaning of article L. 233- 3 of the French Commercial Code (Code de ~~Commerce~~ **commerce**) — of a French company, (b) the acquisition of all or part of a branch of activity of a French company, or (c) for individuals who are not nationals of a Member State of the European Union or of a State party to the agreement on the European Economic Area that has entered into an administrative assistance agreement with France and / or are not domiciled in one of these States, or for legal entities of which at least one of the members of the control chain is not governed by the law of one of these States or is not a national and / or is not domiciled there, to cross the threshold of 25 % of the voting rights of a French company, or (d) for individuals who are not nationals of a Member State of the EU or of a State party to the agreement on the EEA that has entered into an administrative assistance agreement with France and / or are not domiciled in one of these State, or for legal entities of which at least one of the members of the control chain is not governed by the law of one of these States or is not a national and / or is not domiciled there, to cross the threshold of 10 % of the voting rights of a French company whose shares are admitted to trading on a regulated market and (iii) whose activities concern, even occasionally, the research and development of so- called critical technologies, such as biotechnologies, and considered essential to the protection of public health, is subject to prior authorization by the French Minister of the Economy (~~Ministère~~ **ministère** de l' ~~Economie~~ **Économie**). The French Decree No. 2023- 1293 of December 28, 2023 has made permanent the temporary regime under French Decree No. 2022- 1622 of December 23, 2022, which expired on December 31, 2023. The crossing of the threshold of 10 % of the voting rights of French companies whose shares are admitted to trading on a regulated market is subject to a fast track review procedure (filing of a simplified form, delay for the Minister to respond limited to 10 days, transaction deemed authorized in the absence of a response at the end of the delay). If an investment in the Company requiring the prior authorization of the Minister of the Economy is made without such authorization having been granted, the Minister of the Economy may cancel the transaction or order (possibly under financial penalty) the investor concerned (i) to submit an application for authorization, (ii) to have the previous situation restored at its own expense or (iii) to modify the investment. In addition, the Minister may impose undertakings and conditions on the investor (including regular reporting commitments). The investor concerned could also be declared criminally liable and be sanctioned, in particular, by exclusion from any public contract or by a fine which may not exceed the highest of the following three amounts: (i) twice the amount of the investment concerned, (ii) 10 % of the Company' s annual pre- tax revenues and (iii) **€** 5 million ~~euros~~ (for a company) or **€** 1 million ~~euros~~ (for an individual). The application of these regulations is likely to constitute a potential barrier to investments made by investors located outside the European Economic Area and could therefore limit the Company' s access to sources of financing. U. S. Investors may have difficulty enforcing civil liabilities against our company and directors and senior management. Certain members of our board of directors and senior management, and those of our subsidiaries, are non- residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U. S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U. S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U. S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a ~~96~~ claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U. S. law, is applicable to the claim. Further, if U. S. law is found to be applicable, the content of applicable U. S. law must be proved as a fact, which can be a time- consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U. S. securities laws in original actions or judgments of U. S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U. S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States. We are a French company with limited liability. Our corporate affairs are governed by our by-laws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our board of directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U. S. jurisdictions. For example, in the performance of its duties, our board of directors is required by French law to consider the interests of our company, our shareholders, employees and other stakeholders, rather than solely our shareholders and / or creditors. It is possible that some of these parties will have interests that are different from, or are in addition to, your interests as a shareholder. We are a " smaller reporting company, " and the reduced disclosure requirements applicable to smaller reporting companies may make our ADSs less attractive to investors. We are currently a " smaller reporting company " as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We will be a smaller reporting company and may take advantage of the scaled disclosures available to smaller reporting companies for so long as (i) the market value of our voting and non- voting ordinary shares held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter or (ii) (a) our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and (b) the market value of our voting and non- voting ordinary shares held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter. We are permitted and intend to rely on

exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These scaled disclosure requirements include, but are not limited to, the following: • not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, or Section 404; • reduced disclosure obligations regarding financial information; and • reduced disclosure obligations regarding executive compensation. We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our ADSs less attractive if we rely on certain or all of these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ADS price may be more volatile. ~~97~~ **U. S. holders may suffer adverse tax consequences if we are characterized as a passive foreign investment company. Under the U. S. Internal Revenue Code of 1986, as amended, or the Code, we will be a passive foreign investment company, or PFIC, for any taxable year in which, after the application of certain " look- through " rules with respect to subsidiaries, either (i) 75 % or more of our gross income consists of " passive income, " or (ii) 50 % or more of the average quarterly value of our assets, including cash, consists of assets that produce, or are held for the production of, " passive income. " Passive income generally includes interest, dividends, rents, certain non- active royalties and capital gains. Whether we will be a PFIC in any year depends on the composition of our income and the nature and composition of our assets, which we expect may vary substantially over time. Based on the composition of our gross income and the nature and composition of our gross assets, we believe that we may have been a PFIC for the taxable year ending December 31, 2024. Because the determination of our PFIC status is based on complicated provisions of the Code and applicable administrative authorities, there can be no assurance that our conclusions concerning our PFIC status for the taxable year ending December 31, 2023 are correct and will not be successfully challenged by applicable tax authorities, and we cannot provide any assurance regarding our PFIC status for the current taxable year or any future taxable year. If you are a shareholder that is a United States person for U. S. federal income tax purposes, or a U. S. holder during a taxable year when the Company is considered a PFIC, then regardless of whether we continue to be characterized as a PFIC in subsequent taxable years, you may suffer adverse tax consequences, including the treatment of gains realized on the sale of our ADSs as ordinary income, rather than as capital gain, the inapplicability of the preferential rate that otherwise would be applicable to dividends received on our ADSs by individual U. S. holders, the addition of interest charges to the tax on such gains and certain distributions, and additional reporting requirements. A U. S. holder in certain circumstances may mitigate the adverse tax consequences of the PFIC rules by filing an election to treat the PFIC " qualified electing fund ", or as a QEF, or, if shares of the PFIC are " marketable stock " for purposes of the PFIC rules, by making a mark- to- market election with respect to the shares of the PFIC. For any taxable year in which we are a PFIC, we will determine whether we will provide to U. S. holders the information required to make a QEF election; for the taxable year ending December 31, 2024, we have provided that information. However, there is no assurance that such information will be provided in future taxable years, and prospective investors should not assume that a QEF election will be available. U. S. Holders are strongly urged to consult with, and rely solely upon, their personal tax advisors regarding the implications of the tax provisions applicable to U. S. persons who own, directly or indirectly, interests in a foreign corporation that is or may become a PFIC.**