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

# FORM 20-F

**(Mark One)**

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

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

**For the fiscal year ended December 31, 2018**

**OR**

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

**For the transition period from to**

**OR**

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of event requiring this shell company report**

**Commission File Number 001-36697**

# DBV TECHNOLOGIES S.A.

**(Exact name of registrant as specified in its charter and translation of registrant's name into English)**

**France**
**(Jurisdiction of incorporation or organization)**

**177-181 avenue Pierre Brossolette**
**92120 Montrouge France**
**(Address of principal executive offices)**

**Mr. Daniel Tassé**
**Chief Executive Officer and Director**
**DBV Technologies S.A.**
**177-181 avenue Pierre Brossolette**
**92120 Montrouge France**
**Tel: +33 1 55 42 78 78 Fax: +33 1 43 26 10 83**
**(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)**

**Securities registered or to be registered pursuant to Section 12(b) of the Act.**

| Title of each class | Name of each exchange on which registered |
|---|---|
| **American Depositary Shares, each representing one-half of one ordinary share, nominal value €0.10 per share** | **The Nasdaq Stock Market LLC** |
| **Ordinary shares, nominal value €0.10 per share*** | **The Nasdaq Stock Market LLC*** |

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

**Securities registered or to be registered pursuant to Section 12(g) of the Act. None**

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

**Ordinary shares, nominal value €0.10 per share: 30,157,777 as of December 31, 2018**

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

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

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

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

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

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

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

| U.S. GAAP ☐ | International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ | Other ☐ |
|---|---|---|

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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## INTRODUCTION

Unless otherwise indicated, "DBV," "the company," "our company," "we," "us" and "our" refer to DBV Technologies S.A. and its consolidated subsidiary.

We own various trademark registrations and applications, and unregistered trademarks and servicemarks, including," "Viaskin®," "EPIT®," "DBV Technologies®", "Abyldis®" and our corporate logo. All other trademarks or trade names referred to in this Annual Report on Form 20-F are the property of their respective owners. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 20-F are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report on Form 20-F may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our consolidated financial statements are presented in euros. All references in this Annual Report on Form 20-F to "$," "US$," "U.S.$," "U.S. dollars," "dollars" and "USD" mean U.S. dollars and all references to "€" and "euros" mean euros, unless otherwise noted. Throughout this Annual Report on Form 20-F, references to ADSs mean ADSs or ordinary shares represented by ADSs, as the case may be.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Annual Report on Form 20-F, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report on Form 20-F, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the timing or likelihood of regulatory filings and approvals, including with respect to our anticipated submission of a Biologics License Application to the U.S. Food and Drug Administration for Viaskin® Peanut;
- our ability to continue as a going concern;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to advance our Viaskin® manufacturing capabilities, manufacture clinical and commercial supplies of our product candidates and comply with regulatory requirements related to the manufacturing of our product candidates;
- our ability to develop sales and marketing capabilities;
- the commercialization of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding;
- the rate and degree of market acceptance of our product candidates, if approved by regulatory authorities;
- our financial performance;
- developments relating to our competitors and our industry, including competing therapies; and
- other risks and uncertainties, including those listed in this section of this Annual Report on Form 20-F titled "Item 3.D—Risk Factors."

You should refer to the section of this Annual Report on Form 20-F titled "Item 3.D—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 20-F will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Annual Report on Form 20-F and the documents that we reference in this Annual Report on Form 20-F and have filed as exhibits to this Annual Report on Form 20-F completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This Annual Report on Form 20-F contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Annual Report on Form 20-F is generally reliable, such information is inherently imprecise.

## PART I

### Item 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

### Item 2. Offer Statistics and Expected Timetable.

Not applicable.

### Item 3. Key Information.

#### A. Selected Financial Data

Our consolidated audited financial statements have been prepared in accordance with IFRS, as issued by the IASB. We derived the selected statements of consolidated income data for the years ended December 31, 2016, 2017 and 2018 and selected statements of consolidated financial position data as of December 31, 2016, 2017 and 2018 from our consolidated audited financial statements included elsewhere in this Annual Report on Form 20-F. The selected consolidated statement of income data for the years ended December 31, 2014 and 2015 and the selected consolidated financial position data as of December 31, 2014 and 2015 have been derived from our audited consolidated financial statements and notes thereto which are not included in this Annual Report on Form 20-F. This data should be read together with, and is qualified in its entirety by reference to, "Item 5. Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this Annual Report on Form 20-F. Our historical results are not necessarily indicative of the results to be expected in the future.

**Statement of Income (Loss) Data (in thousands, except share and per share data):**

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2014 | 2015 | 2016 | 2017 | 2018 | |
| | Euro | Euro | Euro | Euro | Euro | US$[1] |
| Operating income | € 4,762 | € 6,166 | € 9,084 | € 11,909 | € 14,537 | $ 16,653 |
| Operating expenses: | | | | | | |
| Cost of goods sold | (136) | (128) | — | — | — | — |
| Research and development | (21,143) | (34,234) | (78,828) | (105,232) | (107,171) | (122,776) |
| Sales and marketing | (13) | (491) | (11,282) | (15,824) | (32,169) | (36,853) |
| General and administrative | (8,105) | (16,859) | (35,005) | (35,837) | (41,399) | (47,426) |
| Total expenses | (29,397) | (51,712) | (125,115) | (156,892) | (180,739) | (207,055) |
| Operating (loss) | (24,636) | (45,546) | (116,031) | (144,983) | (166,202) | (190,401) |
| Financial profit (loss) | 624 | 871 | 1,500 | (2,709) | 141 | 162 |
| Income tax | — | — | — | (1) | (15) | (17) |
| Net (loss) | € (24,012) | € (44,674) | € (114,531) | € (147,693) | € (166,076) | $ (190,256) |
| Earnings (loss) per share[2] | | | | | | |
| Basic | € (1.49) | € (2.08) | € (4.68) | € (5.97) | € (5.74) | $ (6.58) |
| Diluted | € (1.49) | € (2.08) | € (4.68) | € (5.97) | € (5.74) | $ (6.58) |
| Number of shares used for computing | | | | | | |
| Basic | 16,086,247 | 21,522,342 | 24,454,850 | 24,757,176 | 28,924,976 | 28,924,976 |
| Diluted | 16,086,247 | 21,522,342 | 24,454,850 | 24,757,176 | 28,924,976 | 28,924,976 |

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

(2) See Note 22 to our financial statements for further details on the calculation of basic and diluted loss per ordinary share.

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

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

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

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**D. Risk Factors**

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

**Risks Related to Our Financial Condition and Capital Requirements**

***We Have Incurred Significant Losses Since Our Inception And Anticipate That We Will Continue To Incur Significant Losses For The Foreseeable Future.***

We are a clinical-stage biopharmaceutical company, and we have not yet generated significant income from operating activities. We have incurred net losses in each year since our inception in 2002, including net losses of €114.5 million, €147.7 million and €166.1 million for the years ended December 31, 2016, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit and reserves of €421 million.

We have devoted most of our financial resources to research and development, including our clinical and pre-clinical development activities. To date, we have financed our operations primarily through the sale of equity securities, obtaining public assistance in support of innovation, such as conditional advances from OSEO

Innovation, or OSEO, reimbursements of research tax credit claims and strategic collaborations. The amount of our future net losses will depend, in part, on the pace and amount of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations, or additional grants or tax credits. While we have completed a pivotal Phase III trial to evaluate the safety and efficacy of Viaskin® Peanut, it may be a few years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for any approved products in those markets.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, including Viaskin® Peanut;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, especially in North America;
- continue our research, pre-clinical and clinical development of our product candidates;
- expand the scope of our current clinical trials for our product candidates;
- initiate additional pre-clinical, clinical or other studies for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain new and existing skilled personnel;
- create additional infrastructure to support our operations as a public company; and
- experience any delays or encounter issues with any of the above.

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

***We Will Require Additional Funding, Which May Not Be Available On Acceptable Terms, Or At All. Failure To Obtain This Necessary Capital When Needed May Force Us To Delay, Limit Or Terminate Our Product Development Efforts Or Other Operations.***

We are currently advancing our product candidates through pre-clinical and clinical development. Developing product candidates is expensive, lengthy and risky, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we seek regulatory approval for Viaskin® Peanut and advance Viaskin® Milk through clinical development. Furthermore, if we obtain marketing approval for Viaskin® Peanut or any other product candidate that we may develop, we expect our commercialization expenses related to product sales, marketing, distribution and manufacturing to increase significantly as we establish the appropriate infrastructure to commercialize.

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

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

Additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our ADSs or ordinary shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidate or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain sufficient funding on a timely basis, we may be required to scale back our operating plan, significantly curtail, delay or discontinue one or more of our research or development programs or the launch and commercialization of Viaskin® Peanut in North America, if approved, or the commercialization of any other product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

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

***We Are Limited In Our Ability To Raise Additional Share Capital, Which May Make It Difficult For Us To Raise Capital To Fund Our Operations.***

Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. As discussed further under "Item 10. B—Memorandum and Articles of Association," our board of directors may be precluded from issuing additional ordinary shares without first obtaining shareholders' approval.

In addition, the French Commercial Code imposes certain limitations on our ability to price any offering of our share capital without preferential subscription right (*sans droit préférentiel de souscription*), which limitation may prevent us from successfully completing any such offering. Specifically, under the French Commercial Code, unless the offering is less than 10% of issued share capital, securities cannot be sold in an offering at a price that is more than a 5% discount to the volume weighted average trading price on Euronext Paris over the last three trading days preceding the commencement of the marketing of the transaction. In addition, the combined shareholders' meeting dated June 22, 2018 granted authority to our board of directors to increase our share capital up to 20% of issued share capital, if the investors in such offering fit within a category of persons meeting certain characteristics. In this case securities cannot be sold in such an offering at a price that is more than a 15% discount to (i) the average trading price on Euronext Paris over five consecutive trading days choosen among the last thrity trading sessions preceding the commencement of the marketing of the transaction or (ii) the weighted average trading price the day preceding the commencement of the marketing of the transaction.

***We Are Obligated To Develop And Maintain A System Of Effective Internal Controls Over Financial Reporting. These Internal Controls May Be Determined To Be Not Effective, Which May Adversely Affect Investor Confidence In Our Company And, As A Result, The Value Of Our Ordinary Shares And ADSs.***

We have been and are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting on an annual basis. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective and would be required to disclose any material weaknesses identified in Management's Report on Internal Control over Financial Reporting. While we have established certain procedures and control over our financial reporting processes, we cannot assure you that these efforts will prevent restatements of our financial statements in the future.

Our independent registered public accounting firm is also required, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. For future reporting periods, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective, investors could lose confidence in the accuracy and completeness of our financial reports, which could cause the price of our ordinary shares and ADSs to decline, and we could be subject to sanctions or investigations by regulatory authorities, including the SEC and Nasdaq. Failure to remediate any material weakness in our internal control over financial reporting, or to maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***If We Do Not Obtain The Capital Necessary To Fund Our Operations, We Will Be Unable To Successfully Develop, Pursue Regulatory Approval For, And Commercialize, Our Biopharmaceutical Products.***

The development of biopharmaceutical products is capital-intensive. We anticipate that we may require additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- progress in, and the costs of, our pre-clinical studies and clinical trials and other research and development programs, particularly as we seek regulatory and marketing approvals for our product candidates that successfully complete clinical trials, including Viaskin® Peanut;
- the costs of establishing, or contracting for, sales, marketing and distribution capabilities if we obtain regulatory approvals to market our product candidates, especially in North America;
- the scope, prioritization and number of our research and development programs;
- the achievement of milestones or occurrence of other developments that trigger payments under our existing collaboration agreements, and any additional collaboration agreements we may enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under our existing collaboration agreements and future collaboration agreements, if any;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights; and
- the costs of securing manufacturing arrangements for commercial production.

Until we can generate significant continuing revenues, we expect to satisfy our future cash needs through collaboration arrangements, sales of our securities, debt financings, obtaining public assistance in support of innovation, such as conditional advances from OSEO, and reimbursements of research tax credit claims, or by licensing one or more of our future product candidates. Uncertainty and dislocations in the financial markets have generally made equity and debt financing more difficult to obtain, and may have a material adverse effect on our ability to meet our future fundraising needs. We cannot be certain that additional funding will be available to us on acceptable terms, if at all. If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. Additional funding, if obtained, may significantly dilute existing shareholders if that financing is obtained through issuing equity or instruments convertible into equity.

***Our Product Development Programs For Candidates May Require Substantial Financial Resources And May Ultimately Be Unsuccessful.***

In addition to the development of our lead product candidates, we have commenced a number of proof-of-concept trials in the field of inflammatory and autoimmune diseases. In November 2015, Dr. Jonathan Spergel from the Children's Hospital of Philadelphia, or CHOP, initiated the Study of Viaskin® Milk in Milk-Induced Eosinophilic Esophagitis, or SMILEE, a Phase IIa clinical trial assessing the safety and efficacy of Viaskin® Milk for the treatment of milk-induced eosinophilic esophagitis, with findings presented in December 2018 and February 2019. We also investigated the use of Viaskin® rPT for the reactivation of immunity against Bordetella pertussis (whooping cough) in healthy adults. Following the announcement of additional Phase I clinical trial results in September 2018, we evaluated further development pathways, including the optimization of Viaskin® rPT. Our current early-stage development programs also include potential treatments for Crohn's disease and respiratory syncytial virus. These development programs are still in the pre-clinical or proof-of-concept phase and may not result in product candidates we can advance to the clinical development phase. None of our other potential product candidates have commenced clinical trials, and there are a number of U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, regulatory requirements that we must satisfy before we can commence these clinical trials, if at all. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other early-stage development programs may adversely affect our ability to continue development and commercialization of product candidates based on our Viaskin® technology platform, and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. Even if we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA or the EMA.

***The Requirements Of Being A U.S. Public Company May Strain Our Resources, Divert Management's Attention And Affect Our Ability To Attract And Retain Executive Management And Qualified Board Members.***

As a U.S. public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not previously incur. We are subject to the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly if we no longer qualify as a foreign private issuer. The Exchange Act requires that, as a public company, we file annual, semi-annual and current reports with respect to our business, financial condition and result of operations. However, as a foreign private issuer, we are not required to file quarterly reports with respect to our business, financial condition and results of operations. We currently make annual and semi-annual filings with respect to our listing on Euronext Paris. Unless otherwise required by the Exchange Act or the listing rules of the Nasdaq Global Select Market, we do not expect to file quarterly financial reports, but have and expect to continue to file financial reports on an annual and semi-annual basis. As a result of being a U.S. public company, management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations.

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

internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. We have limited experience complying with Section 404, and such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our independent registered public accounting firm is also required, pursuant to Section 404 of the Sarbanes-Oxley Act, to report on the effectiveness of our internal control over financial reporting.

Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, or if our independent registered public accounting firm is unable to express an opinion that our internal controls over financial reporting are effective, the market price of our ordinary shares and ADSs could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC or other applicable regulatory authorities and our business could be harmed.

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

As a result of disclosure of information in filings required of a U.S. public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be adversely affected, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and results of operations.

Further, being a U.S. public company and a French public company has an impact on disclosure of information and compliance with two sets of applicable rules. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

**Risks Related to Product Development, Regulatory Approval and Commercialization**

***We Depend Almost Entirely On The Successful Development Of Our Novel Viaskin® Technology. We Cannot Be Certain That We Will Be Able To Obtain Regulatory Approval For, Or Successfully Commercialize, Viaskin® Products.***

We currently have no drug or biological product approved for sale and may never be able to develop a marketable drug or biological product. While we plan to seek regulatory approval for Viaskin® Peanut, one of our two lead Viaskin® technology-based product candidates for which we have completed a pivotal Phase III trial, we cannot assure you that Viaskin® Peanut will successfully complete the FDA regulatory approval process and be commercialized. It is also possible that the FDA may require that we complete additional clinical trials of Viaskin® Peanut prior to considering Viaskin® Peanut for approval. Our other lead Viaskin® technology-based product candidate, Viaskin® Milk, is currently in clinical development. Our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of Viaskin® Peanut and Viaskin® Milk. Viaskin® Milk will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence its commercialization. Our other product candidates, such as Viaskin® Egg or Viaskin® rPT, are still in pre-clinical or early proof-of-concept phase development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical testing and clinical trials that, among other things, the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing requirements and surveillance, including the completion of pediatric studies to satisfy both U.S. and EMA requirements, which will require the expenditure of substantial resources. Of the large number of drugs in development in the United States, only a small percentage successfully

completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that Viaskin® Peanut, Viaskin® Milk, or any other of our product candidates will be successfully developed or commercialized.

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

- we may not be able to demonstrate that Viaskin® Peanut or Viaskin® Milk is safe and effective in treating food allergies, to the satisfaction of the FDA;
- the results of our clinical trials or the clinical trials conducted by third party academic institutions and included in our application package may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may require that we conduct additional clinical trials;
- the FDA may not approve the formulation, labeling or specifications of either Viaskin® Peanut or Viaskin® Milk;
- the clinical research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may find the data from pre-clinical studies and clinical trials from either Viaskin® Peanut or Viaskin® Milk insufficient to demonstrate that the clinical or other benefits of either product candidate outweighs its respective safety risks;
- the FDA may disagree with our analysis or interpretation of data from our pre-clinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our BLA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA may restrict the use of our products to a narrow population;
- the FDA or the applicable foreign regulatory agency may not approve the manufacturing processes or facilities of our own or of third-party manufacturers with which we contract, or may issue inspectional findings that require significant expense and time to address; or
- the FDA may change its approval policies or adopt new regulations. Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any of our product candidates based on our Viaskin® technology platform. Moreover, because our business is almost entirely dependent upon Viaskin® technology, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

In October 2017, we announced topline results from PEPITES, in which we observed a statistically significant response with a favorable tolerability profile. However, the primary endpoint, which evaluates the 95% confidence interval, or CI, in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the trial's Statistical Analysis Plan submitted to the FDA. As such, any submission we make to the FDA or other regulatory agency for approval based on the PEPITES trial may be subject to such regulatory body's interpretation of the CI interval.

In October 2018, we announced the submission of a BLA to the FDA for Viaskin® Peanut for the treatment of peanut allergy in children four to 11 years of age. In December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls. Based on the progress in addressing the FDA's guidance, we anticipate compiling the required information for the submission of our BLA for Viaskin® Peanut in the third quarter of 2019. We cannot assure you that the BLA will be accepted for filing, will be approved or that we will not be required to conduct additional clinical trials of Viaskin® Peanut.

***Our Product Candidates Have Undergone And/Or Will Be Required To Undergo Clinical Trials That Are Time-Consuming And Expensive, The Outcomes Of Which Are Unpredictable, And For Which There Is A High Risk Of Failure. If Clinical Trials Of Our Product Candidates Fail To Satisfactorily Demonstrate Safety And Efficacy To The FDA And Other Regulators, We, Or Our Collaborators, May Incur Additional Costs Or Experience Delays In Completing, Or Ultimately Be Unable To Complete, The Development And Commercialization Of These Product Candidates.***

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

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

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested, especially during the double-blind, placebo-controlled food challenges;
- extension studies on long-term tolerance could invalidate the use of our product, showing Viaskin® does not generate a sustained protective effect;
- the results may not confirm the positive results of earlier testing or trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to establish the safety and efficacy of our product candidates.

The results of pre-clinical studies do not necessarily predict clinical success, and larger and later-stage clinical trials may not produce the same results as earlier-stage clinical trials. The prior clinical trials of our product candidates based on our Viaskin® technology platform showed favorable safety and efficacy data; however, we may have different enrollment criteria in our future clinical trials. As a result, we may not observe a similarly favorable safety and efficacy profile as our prior clinical trials. In addition, we cannot assure you that in the course of potential widespread use in future, some drawbacks would not appear in maintaining production quality, protein stability or allergenic strength. Frequently, product candidates developed by pharmaceutical, biopharmaceutical and biotechnology companies have shown promising results in early pre-clinical studies or clinical trials, but have subsequently suffered significant setbacks or failed in later clinical trials. In addition, clinical trials of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates.

If we do not successfully complete pre-clinical and clinical development, we will be unable to market and sell our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before a BLA may be submitted to the FDA. Although there are a large number of drugs and biologics in development in the United States and other countries,

only a small percentage result in the submission of an NDA or a BLA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed.

***In Our Clinical Trials, We Utilize An Oral Food Challenge Procedure Intentionally Designed To Trigger An Allergic Reaction, Which Could Be Severe Or Life-Threatening.***

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

***Delays, Suspensions And Terminations In Our Clinical Trials Could Result In Increased Costs To Us And Delay Or Prevent Our Ability To Generate Revenues.***

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

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs, and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;
- obtaining sufficient quantities of the drug substance or other materials necessary to conduct clinical trials;
- manufacturing sufficient quantities of a product candidate;
- obtaining permission to proceed from the FDA under an investigational new drug, or IND, application;
- obtaining institutional review board, or IRB, or independent ethics committee approval to conduct a clinical trial at a prospective clinical trial site;
- determining dosing and clinical design and making related adjustments; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

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

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation;
- serious adverse events relating to the double-blind, placebo-controlled food challenge procedure when testing patients for the sensitivity of their allergies;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;

- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory agencies.

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

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

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

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

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

***If Our Product Candidates Are Not Approved By The FDA, We Will Be Unable To Commercialize Them In The United States.***

The FDA must approve any new drug or biologic before it can be commercialized, marketed, promoted or sold in the United States. We must provide the FDA with data from pre-clinical studies and clinical trials that demonstrate that, among other things, our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We must provide data to ensure the identity, strength, quality and purity of the drug substance and drug product. Also, we must assure the FDA that the characteristics and performance of the clinical batches will be replicated consistently in the commercial batches. We will not obtain approval for a product candidate unless and until the FDA approves a BLA, if at all. In October 2018,

we announced the submission of a BLA to the FDA for Viaskin® Peanut for the treatment of peanut allergy in children four to 11 years of age. In December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls. Based on the progress in addressing the FDA's guidance, we anticipate compiling the required information for the submission of our BLA for Viaskin® Peanut in the third quarter of 2019. We cannot assure you that the BLA will be accepted for filing, will be approved or that we will not be required to conduct additional clinical trials of Viaskin® Peanut.

The processes by which regulatory approvals are obtained from the FDA to market and sell a new or repositioned product are complex, require a number of years and involve the expenditure of substantial resources. We cannot assure you that any of our product candidates will receive FDA approval in the future, and the time for receipt of any such approval is currently incapable of estimation.

***A Fast Track Designation By The FDA May Not Actually Lead To A Faster Development Or Regulatory Review Or Approval Process, And It Does Not Increase The Likelihood That Our Product Candidates Will Receive Marketing Approval.***

We have obtained fast track designation from the FDA for the development of Viaskin® Peanut and Viaskin® Milk in pediatric populations, and we may pursue that designation for other product candidates as well. If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe our product candidates are eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do have fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A fast track designation affords the possibility of rolling review, enabling theFDA to review portions of our marketing application before submission of a complete application, and priority review if supported by clinical data at the time of our BLA submission. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

***A Breakthrough Therapy Designation By The FDA For Our Product Candidates May Not Lead To A Faster Development Or Regulatory Review Or Approval Process, And It Does Not Increase The Likelihood That Our Product Candidates Will Receive Marketing Approval.***

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

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

***The Approval Process Outside The United States Varies Among Countries And May Limit Our Ability To Develop, Manufacture And Sell Our Products Internationally. Failure To Obtain Marketing Approval In International Jurisdictions Would Prevent Our Product Candidates From Being Marketed Abroad.***

In order to market and sell our product candidates in the European Union and many other jurisdictions, we, and our collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the United States. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the United States, or we may simultaneously seek regulatory approvals in the United States and other countries. If we or our collaborators seek marketing approvals for a product candidate outside the United States, we will be subject to the regulatory requirements of health authorities in each country in which we seek approvals. With respect to marketing authorizations in Europe, we will be required to submit a European Marketing Authorization Application, or MAA, to the EMA which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approvals may differ from that required to obtain FDA approval.

Pursuing regulatory approvals from health authorities in countries outside the United States is likely to subject us to all of the risks associated with pursuing FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

***Even If We, Or Our Collaborators, Obtain Marketing Approvals For Our Product Candidates, The Terms Of Approvals And Ongoing Regulation Of Our Products May Limit How We Or They Market Our Products, Which Could Materially Impair Our Ability To Generate Revenue.***

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize the product, or may be required to carry a warning in its labeling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we and our collaborators will continue to expend time, money and effort in all areas of regulatory compliance.

***Any Of Our Product Candidates For Which We, Or Our Collaborators, Obtain Marketing Approval In The Future Could Be Subject To Post-Marketing Restrictions Or Withdrawal From The Market And We, And Our Collaborators, May Be Subject To Substantial Penalties If We, Or They, Fail To Comply With Regulatory Requirements Or If We, Or They, Experience Unanticipated Problems With Our Products Following Approval.***

Any of our product candidates for which we, or our collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-marketing requirements and commitments, labeling, advertising and promotional activities for such products, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval will be subject to limitations on the indicated uses for which the product may be marketed or may be subject to other conditions of approval, including the FDA requirement to implement a REMS to ensure that the benefits of a drug or biological product outweigh its risks.

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

and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, market any of our product candidates for which we, or they, receive marketing approval for treatment other than their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

***If We Do Not Achieve Our Projected Development And Commercialization Goals In The Timeframes We Announce And Expect, The Commercialization Of Our Product Candidates May Be Delayed, And Our Business Will Be Harmed.***

We sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives for planning purposes. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals, if any, by the FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our product candidates may be delayed, our business and results of operations may be harmed, the trading price of the ADSs or ordinary shares may decline.

***Access To Raw Materials And Products Necessary For The Conduct Of Clinical Trials And Manufacturing Of Our Product Candidates Is Not Guaranteed.***

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

***Relying On Third-Party Manufacturers May Result In Delays In Our Clinical Development Or Commercialization Efforts.***

Developing and commercializing new medicines entails significant risks and expenses. Our clinical trials may be delayed if third-party manufacturers are unable to assure a sufficient quantity of the drug product to meet our study needs. Currently, we have only one manufacturer, Sanofi S.A., or Sanofi, of the active pharmaceutical ingredients, or API, used in our Viaskin® product candidates, such as peanut protein extract and unmodified allergen milk extract. If Sanofi cannot manufacture the active pharmaceutical ingredients as required by us in a timely manner, we may not be able to find a substitute manufacturer on a timely basis and our clinic trials may be delayed. Further, we are aware that Sanofi has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp (acquired by Merck), and Aimmune Therapeutics. This potential competitive dynamic may make Sanofi less inclined to continue or renew their manufacturing arrangement with us on commercially reasonable terms or at all and, notwithstanding contractual protections, Sanofi may be able to utilize knowledge gained through their relationship with us in furtherance of their development of competitive therapies.

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

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

Once regulatory approval is obtained, a marketed product and its manufacturer are subject to continual review. The discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Any manufacturers with which we contract are required to operate in accordance with FDA-mandated current good manufacturing practices, or cGMPs. A failure of any of our contract manufacturers to establish and follow cGMPs and to document their adherence to such practices may lead to significant delays in the launch of products based on our product candidates into the market. Moreover, the constituent parts of a combination product retain their regulatory status (as a biologic or device, for example) and, as such, we or our contract manufacturers may be subject to additional requirements in the Quality System Regulation, or QSR, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. Failure by third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, revocation or suspension of marketing approval for any products granted pre-market approvals, seizures or recalls of products, operating restrictions, and criminal prosecutions.

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

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

***We Rely, And Will Rely In The Future, On Third Parties To Conduct Our Clinical Trials And Perform Data Collection And Analysis, Which May Result In Costs And Delays That Prevent Us From Successfully Commercializing Product Candidates.***

We rely, and will rely in the future, on medical institutions, clinical investigators, CROs, contract laboratories and collaborators to perform data collection and analysis and others to carry out our clinical trials. Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

***Even If Collaborators With Which We Contract In The Future Successfully Complete Clinical Trials Of Our Product Candidates, Those Candidates May Not Be Commercialized Successfully For Other Reasons.***

Even if we contract with collaborators that successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including:

- failing to receive regulatory approval to market them as drugs;
- being subject to proprietary rights held by others;
- failing to obtain approval from regulatory authorities on the manufacturing of our products;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable;
- failing to compete effectively with products or treatments commercialized by competitors; or
- failing to show long-term risk/benefit ratio of our products.

***Our Viaskin® Product Candidates May Not Be Able To Be Manufactured Profitably On A Large Enough Scale To Support Commercialization.***

To date, our Viaskin® product candidates have only been manufactured at a scale which is adequate to supply our research activities and clinical trials. There can be no assurance that the procedures currently used to manufacture our product candidates will work at a scale which is adequate for commercial needs and we may encounter difficulties in the production of Viaskin® patches due to our or our partners' manufacturing capabilities. We have not built commercial-scale manufacturing facilities, and we have limited manufacturing experience with Viaskin® patches.

We rely on a single supplier to produce, or contract for the production of, active ingredients for our clinical trials and for our commercial supplies of any future approved products. Even if we were to obtain access to quantities of active ingredients sufficient to allow us otherwise to expand our Viaskin® manufacturing capabilities, we may not be able to produce sufficient quantities of the product at an acceptable cost, or at all. In the event our Viaskin® product candidates cannot be manufactured in sufficient quantities for commercialization, our future prospects could be significantly impacted and our financial prospects would be materially harmed.

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

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

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

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

***Our Product Candidates Are Regulated As Biological Products, Or Biologics, Which May Subject Them To Competition Sooner Than Anticipated.***

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

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

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

***Even If Any Of Our Product Candidates Are Commercialized, They May Not Be Accepted By Physicians, Patients, Or The Medical Community In General. Even If We, Or Our Collaborators, Are Able To Commercialize Our Product Candidates, The Products May Become Subject To Market Conditions That Could Harm Our Business.***

Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing drugs or treatments. We cannot predict the degree of market acceptance of any product candidate that receives marketing approval, which will depend on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of the product;

- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the coverage and reimbursement policies of government and commercial third-party payors pertaining to the product; and
- the market price of our product relative to competing treatments.

***We Face Substantial Competition From Companies With Considerably More Resources And Experience Than We Have, Which May Result In Others Discovering, Developing, Receiving Approval For, Or Commercializing Products Before Or More Successfully Than Us.***

The biopharmaceuticals industry is highly competitive. Numerous biopharmaceutical laboratories, biotechnology companies, institutions, universities and other research entities are actively involved in the discovery, research, development and marketing of therapeutic responses to treat allergies, making it a highly competitive field. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Although we believe we are currently in a unique position with respect to the testing and treatment of food allergies in young children, established competitors may invest heavily to quickly discover and develop novel compounds that could make the Viaskin® patch products obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to Viaskin® patch products. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

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

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

To our knowledge, other pharmaceutical and biotechnology companies are also seeking to develop food allergy treatments. For example, Aimmune Therapeutics, Inc., or Aimmune, reported topline results from its Phase III trial evaluating the safety and efficacy of its OIT product candidate, AR101, in peanut allergic patients in February 2018. In March 2019, Aimmune announced that its BLA for AR101 was accepted for review by the FDA. To our knowledge, the company uses a formulation of peanut flour for oral administration intended for oral desensitization to peanut. We are also aware of other companies developing OIT product candidates, as well as other companies that are working on recombinant peanut proteins capable of initiating an attenuated immune response of using subcutaneous administration. We are also aware that Sanofi has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp., (acquired by Merck), and may pose a competitive risk to our products in the future. Aimmune also announced a clinical collaboration with Regeneron Pharmaceuticals, Inc. and Sanofi to study AR101 treatment with dupilumab in peanut allergic patients, and commenced a Phase II clinical trial in October 2018 under this collaboration. We believe that Regeneron and Sanofi are also planning to study dupilumab as a monotherapy in the treatment of peanut allergic patients. In August 2018, Genentech, Inc. and Novartis Pharmaceuticals Corporation announced that the FDA granted breakthrough designation for Xolair for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies. The companies plan to initiate a potentially pivotal trial in multiple food allergies. In March 2018, AnaptysBio, Inc. announced top-line proof-of-concept data for its ongoing Phase IIa trial to evaluate the safety of its IL-33 inhibitor product candidate, ANB020, in severe adult peanut allergic patients. In August 2018, AnaptysBio announced that it will deprioritize the development of ANB020 in peanut allergy.

***Government Restrictions On Pricing And Reimbursement, As Well As Other Healthcare Payor Cost-Containment Initiatives, May Negatively Impact Our Ability To Generate Revenues If We Obtain Regulatory Approval To Market A Product.***

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

- our ability or our collaborators' ability to set a price we believe is fair for our products, if approved;
- our ability or our collaborators' ability to obtain and maintain market acceptance by the medical community and patients;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

Sales of our products, when and if approved for marketing, will depend, in part, on the extent to which our products will be covered by third-party payors, such as federal, state, and foreign government health care programs, commercial insurance and managed healthcare organizations. There may be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Limited third-party reimbursement for our product candidates or a decision by a third-party payor not to cover our product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

Various provisions of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or ACA, were designed to impact the provision of, or payment for, health care in the United States, including expanded Medicaid eligibility, subsidized insurance premiums, provided incentives for businesses to provide health care benefits, prohibited denials of coverage due to pre-existing conditions, established health insurance exchanges, and provided additional support for medical research. With regard to biopharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA. For example, since January 2017, President Trump signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Additionally, on December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017, or Tax Act, which includes a provision repealing the individual mandate to maintain health insurance coverage under the ACA effective January 1, 2019. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While neither the Texas District Court Judge, Trump administration nor CMS have stated that the ruling will have an immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts will impact the ACA. We continue to evaluate how the ACA and recent efforts to limit the implementation of the ACA will impact our business.

Following ACA, both the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, or the ATRA, include, among other things, mandatory reductions in Medicare payments to certain providers. Additionally, in the United States, there have been several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation. The Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The United States Department of Health and Human Services has already started the process of soliciting feedback on some of these measures while concurrently implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, biopharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

We believe that pricing pressures at the federal and state levels in the United States, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential products that may be approved in the future at a price acceptable to us or any of our future collaborators.

***Guidelines And Recommendations Published By Various Organizations May Impact The Use Or Reimbursement Of Viaskin® Peanut, If Approved.***

Government agencies promulgate regulations and guidelines that may be directly applicable to us and any approved products. However, professional societies, practice management groups, insurance carriers, physicians groups, private health and science foundations and organizations involved in various diseases also publish guidelines and recommendations to healthcare providers, administrators and payers, as well as patient communities.

Recommendations by government agencies or other groups and organizations may relate to such matters as usage, dosage, route of administration and use of related therapies, and a growing number of organizations are providing assessments of the value and pricing of pharmaceutical products. These assessments may come from private organizations, such as the Institute for Clinical and Economic Review, or ICER, which publish their findings and offer recommendations relating to the products' reimbursement by government and private payers. ICER has announced that, in April 2019, it plans to publish a draft report assessing the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin® Peanut and a competitor product candidate. The results of the ICER report or any similar recommendations or guidelines may affect our reputation, and any recommendations or guidelines that result in decreased use or reimbursement of Viaskin® Peanut, if approved, could have a material adverse effect on our results of operations and financial condition. In addition, the occurrence of any of the foregoing, or the perception by the investment community or shareholders that such recommendations or guidelines will result in decreased use or reimbursement of Viaskin® Peanut, if approved, could adversely affect the market price of our securities.

***Our Product Candidates May Cause Undesirable Side Effects That Could Delay Or Prevent Their Regulatory Approval, Limit The Commercial Profile Of An Approved Label, Or Result In Significant Negative Consequences Following Marketing Approval, If Any.***

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

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

- regulatory authorities may withdraw or limit their approval of the products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to change the way the products are distributed or administered, conduct additional clinical trials or change the labeling of the products;
- we may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our products; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected products and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues.

***Our Future Growth Depends, In Part, On Our Ability To Penetrate Foreign Markets, Where We Would Be Subject To Additional Regulatory Burdens And Other Risks And Uncertainties.***

Our future profitability will depend, in part, on our ability to commercialize product candidates based on our Viaskin® technology platform in markets within and without the United States and Europe. If we commercialize product candidates based on our Viaskin® technology platform in foreign markets, we would be subject to additional risks and uncertainties, including:

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

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

***We Are Subject To Healthcare Laws And Regulations, Which Could Expose Us To Criminal Sanctions, Civil Penalties, Integrity Obligations, Exclusion from Government Healthcare Programs, Individual Imprisonment, Contractual Damages, Reputational Harm And Diminished Profits And Future Earnings, Among Other Consequences.***

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of Viaskin® patch products, if approved. Our arrangements with such persons and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute Viaskin® patch products, if we obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations include but are not limited to the following:

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

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose certain requirements on covered entities and their business associates, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.
- The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the ACA, that require applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website.
- Analogous state, local or foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements, state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could be costly. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our current and/or future business activities could be subject to challenge under one or more of these laws. If our operations were found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could substantially disrupt our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusion from government funded healthcare programs.

***Changes In Regulatory Requirements, FDA Guidance Or Guidance From Certain European Regulatory Authorities Or Unanticipated Events During Our Clinical Trials Of Viaskin® Patch Products May Occur, Which May Result In Changes To Clinical Trial Protocols Or Additional Clinical Trial Requirements, Which Could Result In Increased Costs To Us And Could Delay Our Development Timeline.***

Changes in regulatory requirements, FDA guidance or guidance from certain European regulatory authorities or unanticipated events during our clinical trials may force us to amend clinical trial protocols or the FDA or certain European regulatory authorities may impose additional clinical trial requirements. Discussions with regulatory authorities have caused us to adjust certain trial protocols. Amendments to our clinical trial protocols would require resubmission to the FDA and IRBs for review and approval, which may adversely impact the cost, timing or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional clinical trials, the commercial prospects for the Viaskin® patch product candidates, or any other product candidates, may be harmed and our ability to generate product revenue will be delayed.

***The FDA And Other Regulatory Agencies Actively Enforce The Laws And Regulations Prohibiting The Promotion Of Off-label Uses. If We Are Found To Have Improperly Promoted Off-label Uses, We May Become Subject To Significant Liability.***

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as Viaskin® patch products, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for Viaskin® patch products as a treatment for a particular allergy, physicians, in their professional medical judgment, may nevertheless prescribe Viaskin® patch products to their patients in a manner that is inconsistent with the approved label. Additionally, it is permissible to share in certain circumstances truthful and nonmisleading information that is consistent with, but not contained in, the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability under the FDCA and other statutory authorities, such as laws prohibiting false claims for reimbursement. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the marketing of Viaskin® patch products, if approved, by restricting off-label promotion, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

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

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

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

***Our Product Development Programs For Candidates Other Than Viaskin® Patch Products May Require Substantial Financial Resources And May Ultimately Be Unsuccessful.***

The success of our business depends primarily upon our ability to identify, develop and commercialize products to treat common food allergies. In addition to the commercialization of Viaskin® Peanut, if approved, and the clinical development of Viaskin® Milk, we may pursue development of our other development programs, including Viaskin® Egg and Viaskin® rPT. None of our other potential product candidates has commenced any clinical trials, and there are a number of FDA requirements that we must satisfy before we can commence clinical trials. Satisfaction of these requirements will entail substantial time, effort and financial resources. We may never satisfy these requirements. Any time, effort and financial resources we expend on our other development programs may adversely affect our ability to continue the commercialization of Viaskin® Peanut, if approved, and the clinical development and commercialization of Viaskin® Milk and we may never commence clinical trials of such development programs despite expending significant resources in pursuit of their development. If we do commence clinical trials of our other potential product candidates, such product candidates may never be approved by the FDA. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations.

***If We Do Not Secure Collaborations With Strategic Partners To Test, Commercialize And Manufacture Certain Product Candidates Outside Of Food Allergies, We May Not Be Able To Successfully Develop Products And Generate Meaningful Revenues.***

A key aspect of our current strategy is to selectively enter into collaborations with third parties to conduct clinical testing, as well as to commercialize and manufacture product candidates outside of food allergies. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We currently have multiple collaboration agreements in effect, including collaborations for the development of applications in the field of respiratory allergies or autoimmune disease, as well as other therapeutic domains, such as vaccines. Collaboration agreements, such as our exclusive global collaboration with Nestlé Health Science, typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize products using our product candidates. Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators may not have sufficient resources or decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid, is not infringed by potential competitors or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; or
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing another party's product candidate.

Thus, collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

Collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure new collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our product candidates and may not generate meaningful revenues.

**Intellectual Property Risks Related to Our Business**

***Our Ability To Compete May Decline If We Do Not Adequately Protect Our Proprietary Rights.***

Our commercial success depends on obtaining and maintaining proprietary rights to our product candidates for the treatment of common food allergies, as well as successfully defending these rights against third-party challenges. We will only be able to protect our product candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our product candidates is uncertain due to a number of factors, including:

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

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

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

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

***Biopharmaceutical Patents And Patent Applications Involve Highly Complex Legal And Factual Questions, Which, If Determined Adversely To Us, Could Negatively Impact Our Patent Position.***

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

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

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

***Developments In Patent Law Could Have A Negative Impact On Our Business.***

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

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

***If We Are Unable To Protect The Confidentiality Of Our Trade Secrets, Our Business And Competitive Position Would Be Harmed.***

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

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

***We Will Not Seek To Protect Our Intellectual Property Rights In All Jurisdictions Throughout The World And We May Not Be Able To Adequately Enforce Our Intellectual Property Rights Even In The Jurisdictions Where We Seek Protection.***

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

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

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

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

***Third Parties May Assert Ownership Or Commercial Rights To Inventions We Develop.***

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

***Third Parties May Assert That Our Employees Or Consultants Have Wrongfully Used Or Disclosed Confidential Information Or Misappropriated Trade Secrets.***

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

***A Dispute Concerning The Infringement Or Misappropriation Of Our Proprietary Rights Or The Proprietary Rights Of Others Could Be Time Consuming And Costly, And An Unfavorable Outcome Could Harm Our Business.***

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

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

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

***We May Infringe The Intellectual Property Rights Of Others, Which May Prevent Or Delay Our Product Development Efforts And Stop Us From Commercializing Or Increase The Costs Of Commercializing Our Product Candidates, If Approved.***

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

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

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

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

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

***Issued Patents Covering Our Product Candidates Could Be Found Invalid Or Unenforceable If Challenged In Court.***

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

**Risks Related to Our Organization, Structure and Operation**

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

As of December 31, 2018, we had 315 full-time employees and we expect to significantly increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, including the commercialization of our product candidates in North America, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

***We Depend On Key Personnel And Attracting Qualified Management Personnel And Our Business Could Be Harmed If We Lose Key Personnel And Cannot Attract New Personnel.***

Our success depends to a significant degree upon the technical and management skills of our officers and key personnel, such as our Chief Executive Officer, our Deputy Chief Executive Officer and our Responsible Pharmacist (qualified person). The loss of the services of any of these individuals would likely have an adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, including a full-time Chief Medical Officer, marketing, technical, and sales executives and personnel. The loss of any of our key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business.

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

retaining key people could be more difficult. Furthermore, we compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

***Our Employees May Engage In Misconduct Or Other Improper Activities, Including Violating Applicable Regulatory Standards And Requirements Or Engaging In Insider Trading, Which Could Significantly Harm Our Business.***

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

***Product Liability And Other Lawsuits Could Divert Our Resources, Result In Substantial Liabilities And Reduce The Commercial Potential Of Our Product Candidates.***

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

***We May Incur Significant Costs From Class Action Litigation.***

The market price for our ordinary shares or ADSs may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development and commercialization efforts or the development and commercialization efforts of our collaborators and/or competitors, the addition or departure of our key personnel, variations in our operating results and changes in market valuations of pharmaceutical and biotechnology companies. For example, in December 2018, we announced that we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls, and our ADS price declined significantly as a result. When the market price of a security has been volatile as the market price for our ordinary shares and ADSs has been, holders of that security have occasionally brought securities class action litigation against the company that issued the security.

For example, a class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint alleges that we and our former Chief Executive Officer, our current Chief Executive Officer and our

Deputy Chief Executive Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our securities between February 14, 2018 and December 19, 2018. We believe that the allegations contained in the complaint are without merit and intend to defend the case vigorously. However, whether or not the plaintiff's claims are successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of our business. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

We may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition. We maintain liability insurance; however, if any costs or expenses associated with this or any other litigation exceed our insurance coverage, we may be forced to bear some or all of these costs and expenses directly, which could be substantial.

***We May Be Subject To Legal Or Administrative Proceedings And Litigation Other Than Product Liability Lawsuits Which May Be Costly To Defend And Could Materially Harm Our Business, Financial Condition And Operations.***

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates we develop. We currently carry product liability insurance coverage for our clinical trials with a €15.0 million annual aggregate coverage limit. Although we maintain such insurance, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the future, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims by us or our partners, licensees or subcontractors, which could prevent or inhibit the commercial production and sale of any of our product candidates that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully.

***Our Failure To Maintain Certain Tax Benefits Applicable To French Technology Companies May Adversely Affect Our Results Of Operations.***

As a French technology company, we have benefited from certain tax advantages, including, for example, the French research tax credit (*crédit d'impôt recherche)*, or CIR. The CIR is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess (if any) may be refunded at the end of a three fiscal-year period. The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented €7.2 million, €9.3 million and €10.8 million as of December 31, 2016, 2017 and 2018, respectively. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR benefit. The French tax authorities may challenge our eligibility to, or our calculation of certain tax reductions and/or deductions in respect of our research and development activities and, should the French tax authorities be successful, we may be liable to additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the French Parliament decides to eliminate, or reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

***We May Be Forced To Repay Conditional Advances Prematurely If We Fail To Comply With Our Contractual Obligations Under The Applicable Innovation Grant Agreements.***

Since inception through December 31, 2018, we have received multiple conditional advances totaling €6.2 million for innovation granted by OSEO, the French Agency for Innovation and part of the Banque Publique d'Investissement. If we fail to comply with our contractual obligations under the applicable innovation grant agreements, including if we lose our exclusive right to commercially develop our product candidates, we could be forced to repay the sums advanced ahead of schedule. Such premature repayment could adversely affect our ability to finance our research and development projects. In addition, we cannot ensure that we will then have the additional financial means needed, the time or the ability to replace these financial resources with others.

***We May Be Exposed To Significant Foreign Exchange Risk. Exchange Rate Fluctuations May Adversely Affect The Foreign Currency Value Of Our ADSs.***

We incur portions of our expenses, and may in the future derive revenues, in currencies other than the euro, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ADSs are quoted in U.S. dollars on the Nasdaq Global Select Market and our ordinary shares are trading in euros on Euronext Paris. Our financial statements are prepared in euros. Fluctuations in the exchange rate between euros and the U.S. dollar will affect, among other matters, the U.S. dollar value and the euro value of our ordinary shares and ADSs.

***We May Use Hazardous Chemicals And Biological Materials In Our Business. Any Claims Relating To Improper Handling, Storage Or Disposal Of These Materials Could Be Time Consuming And Costly.***

Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. For example, in production, the confinement of the electrospray function and the use of the allergen in liquid form make it possible to prevent the allergens from contaminating the environment. However, we cannot assure you that in case of malfunction during the handling, storage or production process, allergen would not be released into the atmosphere and sensitize the persons present in the environment. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state, local or foreign laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

***Our Internal Computer Systems, Or Those Of Our Third-party Contractors Or Consultants, May Fail Or Suffer Security Breaches, Which Could Result In A Material Disruption Of Our Product Development Programs.***

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

***We May Acquire Businesses Or Products, Or Form Strategic Alliances, In The Future, And We May Not Realize The Benefits Of Such Acquisitions.***

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

***European Data Collection Is Governed By Restrictive Regulations Governing The Use, Processing, And Cross-Border Transfer Of Personal Information.***

The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Directive ((EU) 2016/679), or GDPR. This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Union may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, results of operations and financial condition.

***We Are Subject To U.S. And Certain Foreign Export And Import Controls, Sanctions, Embargoes, Anti-Corruption Laws, And Anti-Money Laundering Laws And Regulations. Compliance With These Legal Standards Could Impair Our Ability To Compete In Domestic And International Markets. We Can Face Criminal Liability And Other Serious Consequences For Violations, Which Can Harm Our Business.***

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

**Risks Related to Ownership of Our Ordinary Shares and ADSs**

***The Market Price For The ADSs May Be Volatile Or May Decline Regardless Of Our Operating Performance.***

The trading price of our ADSs and ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of our securities depends on a number of factors, including those described in this "Risk Factors" section, many of which are beyond our control and may not be related to our operating performance.

Our ADSs were sold in our initial public offering on Nasdaq in October 2014 at a price of $21.64 per share, and the price per ADS has ranged from as low as $3.60 and as high as $26.98 during 2018. During this same period, our ordinary share prices have ranged from as low as €7.59 to as high as €47.38. The market price of our securities may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations attributable to inconsistent trading volume levels of the ADSs and/or ordinary shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes in the structure of healthcare payment systems;
- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or ADSs by us, our insiders or our other shareholders; and
- general economic and market conditions.

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

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

Our executive officers, directors, current 5% or greater shareholders and affiliated entities, including entities affiliated with Caisse de Dépots et Consignations, entities affiliated with Baker Bros. Advisors LP, entities affiliated with Perceptive Advisors LLC, entities affiliated with Morgan Stanley, ArrowMark Colorado Holdings, LLC and entities affiliated with Boxer Capital, LLC, together beneficially own approximately 55.6% of our ordinary shares. As a result, these shareholders, acting together, will have significant influence over all matters that require approval by our shareholders, including the election of directors and approval of significant corporate transactions. Corporate action might be taken even if other shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial.

***If Securities Or Industry Analysts Do Not Publish Research Or Publish Inaccurate Or Unfavorable Research About Our Business, The Price Of The ADSs And Trading Volume Could Decline.***

The trading market for our ADSs and ordinary shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades our ADSs or ordinary shares or publishes incorrect or unfavorable research about our business, the price of our ADSs and ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our ADSs or ordinary shares, demand for the our ADSs and ordinary shares could decrease, which could cause the price of our ADSs or ordinary shares or trading volume to decline.

***We Do Not Currently Intend To Pay Dividends On Our Securities And, Consequently, Your Ability To Achieve A Return On Your Investment, If Any, Will Depend On Appreciation In The Price Of The ADSs. In Addition, French Law May Limit The Amount Of Dividends We Are Able To Distribute.***

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ADSs for the foreseeable future and the success of an investment in ADSs will depend upon any future appreciation in its value. Consequently, investors may need to sell all or part of their holdings of ADSs after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that the ADSs will appreciate in value or even maintain the price at which our shareholders have purchased the ADSs. Investors seeking cash dividends should not purchase the ADSs.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our annual financial statements. Please see the section of this Annual Report on Form 20-F titled “Item 10.B—Memorandum and Articles of Association” for further details on the limitations on our ability to declare and pay dividends. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

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

***Future Sales Of Ordinary Shares Or ADSs By Existing Shareholders Could Depress The Market Price Of The ADSs.***

As of December 31, 2018, 30,157,777 ordinary shares were issued and outstanding. Sales of a substantial number of shares of our ordinary shares or ADSs in the public market, or the perception that these sales might occur, could depress the market price of our securities and could impair our ability to raise capital through the sale of additional equity securities. A substantial number of our shares are now generally freely tradable, subject, in the case of sales by our affiliates, to the volume limitations and other provisions of Rule 144 under the Securities Act. If holders of these shares sell, or indicate an intent to sell, substantial amounts of our securities in the public market, the trading price of our securities could decline significantly.

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

***Our By-Laws And French Corporate Law Contain Provisions That May Delay Or Discourage A Takeover Attempt.***

Provisions contained in our by-laws and the corporate laws of France, the country in which we are incorporated, could make it more difficult for a third-party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our by-laws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, a non-French resident as well as any French entity controlled by non-French residents may have to file a declaration for statistical purposes with the French Banque de France. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- the owner of 95% of voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the EEA Agreement, including from the main French Stock Exchange, has the right to force out minority shareholders following a tender offer made to all shareholders;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can only be convened by our chairman or our managing director, if any, or, when no board meeting has been held for more than two consecutive months, by directors representing at least one-third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions; however, this mode of participation (by way of videoconference or teleconference) does not apply to the adoption of decisions taken for the closing of the accounts for the fiscal year, including the consolidated financial statements;
- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our by-laws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations; see the section of this Annual Report on Form 20-F titled "Item 10.B—Memorandum and Articles of Association";
- transfers of shares shall comply with applicable insider trading rules and regulations and in particular with the Market Abuse Directive and Regulation dated April 16, 2014; and

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

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

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

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

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

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis, transferable during a period starting two days prior to the opening of the subscription period or, if that day is not a trading day, the preceding trading day; and ending two days prior to the closing of the subscription period or, 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.

***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.

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

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

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

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

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

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

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

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

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

Certain members of our board of directors and senior management, and those of our subsidiary, are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

***The Rights Of Shareholders In Companies Subject To French Corporate Law Differ In Material Respects From The Rights Of Shareholders Of Corporations Incorporated In The United States.***

We are a French company with limited liability. Our corporate affairs are governed by our by-laws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our board of directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our board of directors is required by French law to consider the interests of our company, our shareholders, employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. See the sections of this Annual Report on Form 20-F titled “Item 10. B—Memorandum and Articles of Association” and “Item 16.G—Corporate Governance.”

***U.S. Holders Of ADSs May Suffer Adverse Tax Consequences If We Are Characterized As A Passive Foreign Investment Company.***

Under the U.S. Internal Revenue Code of 1986, as amended, or Code, we will be a passive foreign investment company, or PFIC, for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets, including cash, consists of assets that produce, or are held for the production of, "passive income." Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains. Whether we will be a PFIC in any year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. Based on the composition of our gross income and gross assets for our 2018 taxable year, the latter determined by reference to the value of the ADSs and shares, we believe that we were not likely a PFIC for the taxable year ending December 31, 2018, and we do not expect to be classified as a PFIC for the taxable year ending December 31, 2019. However, there can be no assurance that we have not been or will not be a PFIC for the current taxable year or any future taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined below) holds ADSs, a U.S. Holder may be subject to adverse tax consequences if a mark-to-market election or a qualified electing fund, or QEF, election has not been made with respect to its ADSs. A U.S. Holder may incur significant additional U.S. federal income taxes on income resulting from certain distributions on, or any gain from the disposition of, such ADSs, as such income generally would be allocated over the U.S. Holder's holding period for its ADSs. The amount allocated to the current taxable year (*i.e.*, the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC would be subject to tax as ordinary income earned in the current year, and all other amounts would be subject to tax at the highest rates of U.S. federal income taxation in effect for such years, with an interest charge then imposed on the resulting taxes in respect of such income. Furthermore, if we are a PFIC for any taxable year during which the U.S. Holder holds ADSs, dividends paid by us would not be eligible for preferential individual rates of U.S. federal income tax. In addition, U.S. Holders that own an interest in a PFIC are required to comply with certain reporting requirements.

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

## Item 4. Information on the Company.

### A. History and Development Of The Company

Our legal and commercial name is DBV Technologies S.A. We were incorporated as a *société par actions simplifiée (S.A.S.)* under the laws of the French Republic on March 29, 2002 for a period of 99 years and subsequently converted on March 13, 2003 into a *société anonyme*. We are registered at the Nanterre Commerce and Companies Register under the number 441 772 522. Our principal executive offices are located at 177-181 avenue Pierre Brossolette, 92120 Montrouge, France, and our telephone number is +33 1 55 42 78 78. Our agent for service of process in the United States is Puglisi & Associates. We also maintain a website at www.dbv-technologies.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not a part of this Annual Report on Form 20-F.

Our actual capital expenditures for the years ended December 31, 2016, 2017 and 2018 amounted to €8.3 million, €7.8 million and €8.6 million, respectively. These capital expenditures primarily consisted of the acquisition of laboratory equipment and industrial tools, the refurbishment of our research and development laboratories, our relocation of our headquarters to Montrouge as well as cash contributions to our liquidity contract. We expect our capital expenditures to increase in absolute terms in the near term as we seek regulatory approval for the commercialization of Viaskin® Peanut, continue to advance our research and development programs and grow our operations. For the near future, our investments will mainly remain in France where our research and development facilities are currently located.

**B. Business Overview**

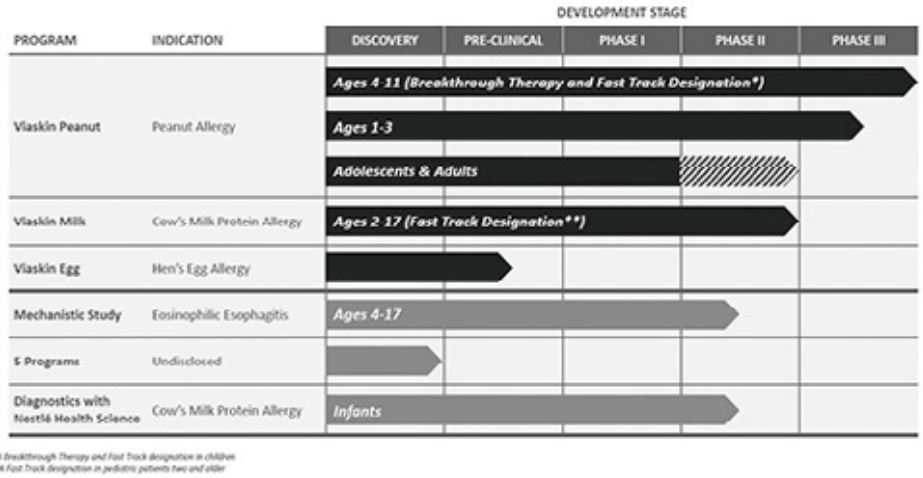
We are a clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin®. Our therapeutic approach is based on epicutaneous immunotherapy, or EPIT®, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin®. We have generated significant data demonstrating that Viaskin®'s mechanism of action is novel and differentiated as it targets specific antigen-presenting immune cells in the skin, called Langerhans cells, which capture the antigen and migrate to the lymph node in order to activate the immune system without allowing passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to address areas of unmet medical need, including in patients suffering from food allergies, for whom safety is paramount as the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as anaphylactic shock.

Our proprietary platform is based on our epicutaneous Viaskin® patch. We have designed and developed this technology internally, for which we have scalable manufacturing capabilities. Viaskin® is an electrostatic patch, which may offer a convenient, self-administered, non-invasive immunotherapy to patients. Once applied on intact skin, Viaskin® forms a condensation chamber, which hydrates the skin and solubilizes the antigen allowing it to penetrate the epidermis, where it is captured by Langerhans cells. Based on numerous scientific publications and our own research, we believe this unique mechanism of action has a favorable safety profile and that it generates a strong immune response that results in allergen desensitization. Our epicutaneous immunotherapy method allows us to develop product candidates addressing food allergies, as well as other unmet medical needs.

According to an expert panel convened by the American Academy of Allergy Asthma and Immunology, or the AAAAI, epidemiological studies suggest that over half of Americans are sensitive to at least one allergen. Allergy is considered a "disease of the developed world" as its increasing incidence is proportional to higher living standards. Based on a paper published by the AAAAI, approximately 3% to 5% of Americans suffer from food allergies, with a number of recent studies suggesting that nearly 6 million or approximately 8% of children have some type of food allergy. Food allergies in particular can lead to extremely dangerous reactions while significantly impairing daily quality of life. According to a paper published in the Immunology and Allergy Clinics of North America, food, mainly peanut, allergies, are responsible for 150 to 200 deaths and about 200,000 emergency room visits every year in the United States. These patients often also experience skin discomfort, asthma symptoms, impaired lung function and gastrointestinal complications, such as sustained bloating, nausea, vomiting and diarrhea. Food allergies can be particularly difficult for young children to manage, and due to their life-threatening nature, severe food allergies can often lead to psychological traumas and social anxiety. In some cases, these allergies can also cause chronic diseases such as failure to thrive in children and an allergic inflammatory condition of the esophagus called eosinophilic esophagitis, or EoE.

We are committed to finding safe, effective and patient-friendly therapies for food-allergic patients, for whom there are no approved treatments. Compared to other allergy treatment approaches, we believe the safety profile of our EPIT® method carried-out via the Viaskin® patch may be able to offer significant therapeutic, tolerability and ease-of-use advantages to these patients. EPIT® can be utilized as an allergy-specific immunotherapy commonly referred to as desensitization. Desensitization consists of repeated administration of small quantities of allergen to decrease allergen reactivity in patients. Currently studied desensitization methods include subcutaneous, sublingual and oral immunotherapy, which often require frequent or prolonged administration in specialized centers. In academic settings some successful cases exist, but large-scale pharmaceutical development in this field has been limited due to both the safety concerns and the commercial viability of these desensitization approaches for the treatment of food allergies. These methods may also be poorly designed for pediatric patients due to their safety profile or the inconvenient method of administration. Most importantly, some of these approaches are also known for triggering severe adverse events related to treatment, including severe anaphylaxis, risking the patient's life during administration. Further, some of these methods have been also associated with an increased risk of adverse long- term treatment effects, such as EoE. As a self-administered treatment with a good safety profile, we believe Viaskin® has positioned us as the company with one of the most advanced clinical programs in food allergies to date.

The following table summarizes our most advanced product candidates:




We are focused on becoming the leader in discovering, developing and commercializing food allergies products. Our pipeline development strategy is based on leveraging Viaskin®'s scientific profile while taking into consideration a combination of target market characteristics, which include allergen prevalence, persistence and severity. We select our target product candidates with the aim to address allergies that have high unmet medical needs.

Our lead product candidate, Viaskin® Peanut, has completed a global Phase III program for the treatment of peanut allergic patients four to 11 years of age. Viaskin® Peanut has obtained fast track designation and breakthrough therapy designation in children from the U.S. Food and Drug Administration, or FDA, which are regulatory designations intended to expedite or facilitate the process of reviewing new drugs and biological products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The European Medicines Agency's, or EMA, Pediatric Committee has also adopted a positive opinion with respect to our Pediatric Investigation Plan, or PIP, for Viaskin® Peanut, which is a prerequisite for the filing of marketing authorization for any new medicinal product in Europe.

In September 2014, we announced topline results for our Viaskin® Peanut's Efficacy and Safety, or VIPES, Phase IIb clinical trial of Viaskin® Peanut for the treatment of peanut allergic patients, which was followed by a full study report presented at the 2015 AAAAI Annual Meeting in Houston, Texas. In October 2016, we announced topline results from the two-year OLFUS-VIPES study evaluating the long-term efficacy and safety profile of Viaskin® Peanut for the treatment of peanut allergic children. OLFUS-VIPES, or OLFUS, is an open-label, follow-up study to VIPES. Following results from our Phase IIb program, we launched a Phase III program designed to assess the efficacy and safety of Viaskin® Peanut in children. As part of our Phase III program development, we initiated the Peanut EPIT® Efficacy and Safety Study, or PEPITES, a pivotal Phase III trial, in December 2015. PEPITES was designed to evaluate the safety and efficacy of Viaskin® Peanut 250 µg in 356 peanut allergic patients four to 11 years of age. In August 2016, we launched the REAL Life Use and Safety of EPIT® (REALISE) study, which was designed to evaluate the use and safety of Viaskin® Peanut 250 µg in routine clinical practice in 393 peanut allergic patients four to 11 years of age.

In October 2017, we announced topline results from PEPITES, in which we observed a statistically significant response with a favorable tolerability profile, with 35.3% of patients responding to Viaskin® Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates = 21.7%; p=0.00001; 95% CI = 12.4% - 29.8%). However, the primary endpoint, which evaluates the 95% confidence interval, or CI, in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the trial's Statistical Analysis Plan submitted to the FDA.

In November 2017, we announced topline safety results from REALISE and that the trial met its primary objective. In the trial, we observed that Viaskin® Peanut was well-tolerated with no new or unexpected adverse events. A favorable safety and tolerability profile was observed, which was comparable with outcomes from previous studies of Viaskin® Peanut 250 µg.

The results from PEPITES and REALISE will form the basis for our planned regulatory submissions in the United States, Europe and other countries for the use of Viaskin® Peanut in peanut allergic patients four to 11 years of age.

In February 2018, we announced that the FDA agreed that the available efficacy and safety data for Viaskin® Peanut supports the submission of a Biologics License Application, or a BLA, for the treatment of peanut allergy in children four to 11 years of age. The FDA provided written responses to the clinical pre-BLA meeting package we submitted. These responses reflect agreement on the content of the clinical module of the BLA for Viaskin® Peanut; however, FDA agreement on the content of the BLA clinical module does not assure that the BLA will be approved and that we will not be required to conduct additional clinical trials of Viaskin® Peanut.

In October 2018, we announced the submission of a BLA to the FDA for Viaskin® Peanut for the treatment of peanut allergy in children four to 11 years of age.

In December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls.

In February 2019, we announced that based on the progress in addressing the FDA's guidance, we expect to submit our BLA for Viaskin® Peanut in the third quarter of 2019.

On October 30, 2018, the Institute for Clinical and Economic Review, or ICER, announced that it plans to assess the comparative clinical effectiveness and value of treatments for peanut allergy, including Viaskin Peanut and a competitor product candidate. ICER plans to publish a draft evidence report on April 9, 2019.

We intend to provide an update on timelines for our European Marketing Authorization Application to the EMA following our BLA submission.

We are also developing Viaskin® Peanut for the treatment of peanut allergy in toddlers one to three years of age. In August 2017, we initiated the EPIT® in Toddlers with Peanut Allergy, or EPITOPE, a Phase III clinical trial assessing the safety and efficacy of Viaskin® Peanut for the treatment of peanut allergic patients one to three years of age. In September 2018, we announced that the independent data and safety monitoring board, or DSMB, completed its planned safety review of Part A of the EPITOPE trial. The DSMB did not identify any safety concerns for patients enrolled in Part A of the trial and recommended that the trial continue as planned with the 250 µg dose selected for investigation in Part B. Following a positive DSMB meeting, we initiated Part B of the EPITOPE trial in October 2018, which will study patients for 12 months. We expect to enroll approximately 400 toddlers for Part B in the United States, Europe, Australia and Canada.

We are developing our second product candidate, Viaskin® Milk, for the treatment of cow's milk protein allergy, or CMPA, in children two to 17 years of age, which received fast track designation from the FDA in September 2016. In November 2014, we initiated a multi-center, double-blind, placebo-controlled, randomized Phase I/II dose-finding trial to study the safety and efficacy of Viaskin® Milk in 198 patients with Immunoglobulin E, or IgE, mediated CMPA, which we refer to as the Milk Efficacy and Safety, or MILES, trial. The MILES (Milk Efficacy and Safety) study was designed to determine a safe and effective dose in two age groups: children ages two to 11 and adolescents ages 12 to 17. In June 2015, we announced completion of Part A of the MILES study, or Phase I, for which the DSMB recommended to continue the study as planned and did not raise any safety concerns, and we launched Part B, or Phase II, in October 2015.

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

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

In addition to our development programs in food allergies, we are exploring the use of our Viaskin® technology for the treatment of inflammatory and autoimmune diseases with high unmet medical need. Human proof-of-concept trials are ongoing with Viaskin® in EoE and as a booster vaccination against Bordetella pertussis (whooping cough) in healthy adults. Our other earlier stage research programs include vaccination for respiratory syncytial virus, as well as potential treatments for Crohn's disease, hemophilia A, celiac disease and type I diabetes.

In an effort to continue diversifying our product candidate pipeline, we are also exploring the use of our technology platform in the development of diagnostic tools for food allergies. In May 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of CMPA in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016.

We intend to commercialize our food allergy product candidates, if approved, independently in North America and certain European countries. In June 2016, we signed a lease for a commercial facility in Summit, New Jersey, which is intended to support the launch and commercialization of Viaskin® Peanut in North America, if the appropriate regulatory approvals are received.

In other geographies and indications outside of food allergies, we may explore selective collaborations with parties who have relevant clinical and commercial expertise in order to maximize shareholder value.

**Our Strategy**

Our goal is to become the leading global biopharmaceutical company focused on discovering, developing, manufacturing and commercializing treatments for severe allergies. Key elements of our strategy are:

- Rapidly Seek Marketing Approval for Viaskin® Peanut— Our Phase III development program for Viaskin® Peanut in peanut allergic children ages four to 11 has been completed. In December 2015, we initiated PEPITES, a pivotal efficacy and safety Phase III trial in peanut allergic children four to 11 years of age. In November 2016, we initiated REALISE, a Phase III safety trial in peanut allergic children four to 11 years of age. We reported results from the PEPITES and REALISE trials in October and November 2017, respectively. We are also exploring additional marketing indications for Viaskin® Peanut in other patient populations as part of our clinical development strategy, and have an ongoing Phase III trial in toddlers one to three years of age, called EPITOPE. In order to potentially expedite development of Viaskin® Peanut, we have pursued and obtained both fast track and breakthrough therapy designations from the FDA for Viaskin® Peanut. We intend to submit our BLA for Viaskin® Peanut in the third quarter of 2019 and seek marketing approval for Viaskin® Peanut for the treatment of peanut allergic children four to 11 years of age.
- Advance the Development of Our Viaskin® Technology Platform into Other Areas of Unmet Medical Need in Food Allergies—We are advancing the clinical development of Viaskin® Milk to address IgE mediated CMPA, which is frequently the first food allergy that appears in early childhood and affects approximately 2% to 3% of the population in developed countries. We initiated MILES in November 2014, and reported results in February 2018. We obtained fast track designation from the FDA for Viaskin® Milk in September 2016 for the treatment of CMPA in children two to 17 years of age. Preclinical development for Viaskin® Egg began in the first half of 2015 and is currently ongoing.

- Become a Fully Integrated Biopharmaceutical Company Focused on the Commercialization of our Viaskin® Food Allergies Product Candidates in the United States and Other Major Markets—We are utilizing our team's unique expertise and knowledge in food allergies to rapidly advance clinical development and approval of our product candidates. In anticipation of commercial launches, we continue to enhance our manufacturing and commercial production capabilities. Given the limited number and targeted nature of the prescribers in our target markets, we currently intend to launch and commercialize our food allergies product candidates with our own specialty sales force.
- Maximize the Value of our Innovative Viaskin® Technology Platform by Building a Broad Immunotherapy Product Pipeline—We are leveraging our expertise in skin immunology science and believe that our Viaskin® technology platform has the potential to support significant product opportunities beyond treatments for food allergies. To support our pipeline innovation strategy, we have commenced a number of proof-of-concept trials in the field of inflammatory and autoimmune diseases, including an investigator-sponsored study at the Children's Hospital of Philadelphia, or CHOP, in EoE, an inflammatory disease of the esophagus, with findings presented in December 2018 and February 2019. In collaboration with the Geneva University Hospitals, or HUG, and BioNet-Asia Co. Ltd., or BioNet, we conducted a Phase I trial of Viaskin® rPT for booster vaccination against pertussis, our first human proof-of-concept trial in the field of boosting vaccination. Initial data was announced in March 2017, with additional data presented in September 2018. We have also advanced a number of pre-clinical indications, which could enable us to broaden our product pipeline, including the development of applications in Crohn's disease, hemophilia A, as well as other early stage research opportunities and collaborations. We expect to selectively collaborate with leading pharmaceutical and biotechnology companies that have deep clinical expertise or extensive commercial infrastructure in other therapeutic areas of interest to us, in order to accelerate product candidate development and maximize shareholder value.

## Our Industry

### *Allergies are a Growing Global Health Problem*

Allergy is considered a "disease of the developed world" as its increasing incidence is proportional to higher living standards. Epidemiological studies suggest that over half of Americans are sensitive to at least one allergen. Environmental and lifestyle changes, urbanization, pollution, dietary changes, development of sanitation standards and decrease in chronic bacterial infections all seem to be factors promoting the rapid increase in prevalence of allergies throughout the developed world.

### *Background on Allergic Reaction*

An allergic reaction is the body's inappropriate immune response to a foreign substance, or an allergen. While, for most people, exposure to an allergen is relatively harmless, for others, exposure to an allergen can provoke an allergic reaction of varying severity. An allergic reaction typically progresses in two stages.

In the first stage, the allergic immune response begins with allergen sensitization. The first time an allergen penetrates the body via the skin or the mucosa, for example, the eyes, respiratory or digestive tracts, the immune system identifies the foreign element as dangerous and begins to produce specific antibodies against it. Antibodies are substances produced by the immune system that recognize and destroy certain foreign elements to which the body is exposed. The immune system produces different types of antibodies targeted to specific allergens. For allergic people, this phenomenon is known as sensitization. In the second stage of an allergic reaction, upon re-exposure to the allergen, the now sensitized immune system is ready to react. The antibody seeks to eliminate the allergen by triggering a collection of defense responses causing an allergic reaction. In various types of allergies, including food allergies, the antibody IgE plays an essential role in the development of the allergic disease. IgE is known for binding to allergens and triggering the release of cellular substances that can cause inflammation, thus triggering a cascade of allergic reactions. Allergic reactions range in severity and include hives, itching, swelling, shortness of breath, vomiting, and cardiac arrhythmia. Reactions vary in duration, and allergy patients experience these symptoms frequently unless treated properly. The most severe allergic reaction is anaphylaxis, which if not treated quickly by epinephrine injection, may progress to anaphylactic shock causing a rapid drop in blood pressure, loss of consciousness and possibly death within a few minutes.

***Current Challenges in the Treatment and Management of Allergy Patients***

*Symptomatic Allergy Treatments and their Limitations*

For food allergies, there are no approved symptomatic or disease-modifying allergy treatments. By contrast, in the case of respiratory allergies, symptomatic allergy treatments, such as antihistamines, bronchodilators and corticosteroids, are among the most widely used treatments in the world. Non-sedating antihistamines such as histamine H1 inhibitors are the mainstay treatment for respiratory allergies. Allegra and Zyrtec are two leading antihistamines treatments. Another method of symptomatic treatment consists of blocking production of IgE, the allergy antibody.

However, all these treatments treat the symptoms of allergies, and are not intended to treat the underlying causes of the allergic reaction itself. As a result, when the treatment course is finished, the patient is once again susceptible to the original allergen and typically will suffer a similar allergic reaction if re-exposed to the original allergen.

*Emergency Treatments and Their Limitations*

Allergies can lead to severe reactions that require the use of treatments that have been designated to treat allergic symptoms during emergency situations, such as severe anaphylactic reactions. Epinephrine, also known as adrenaline, is the most widely used treatment for anaphylactic reactions, and it is usually administered by injection. The most commonly used type of epinephrine injections are Epipen Auto-Injectors, or Epipens, which are indicated for the emergency treatment of severe allergic reactions including sudden anaphylactic shock or for patients with a history of anaphylactic reactions to known triggers. Patients at risk of anaphylaxis are instructed by their physicians on how to recognize the symptoms of anaphylaxis and on when to use the Epipens. Epinephrine injections help relieve the symptoms of anaphylaxis, but they do not treat or help address the underlying causes of the allergic disease.

*Desensitization Allergy Treatments and their Limitations*

Another therapeutic approach for the treatment of allergies is through a type of immunotherapy called desensitization therapy. Desensitization therapy consists of repeated administration of increasing quantities of allergen to decrease reactivity in allergic patients. It is currently recognized by the World Health Organization, or WHO, as the preferred therapeutic treatment for allergies. Desensitization therapy is widely used in respiratory allergies and allergies to insect bites. This treatment is traditionally performed by subcutaneous injections of increasing doses of the allergen at regular intervals in the hospital and under the supervision of a physician. Less invasive methods of administration, including oral drops and sublingual, or under the tongue, tablets, have also been developed to permit a simplified treatment that can be administered at home. For patients allergic to dust mites or pollen, desensitization by injection is the standard method of therapy.

However, while desensitization has shown potential in less severe allergies such as house dust mites or pollen, for food allergies and other severe allergies such as to peanut or milk proteins, existing desensitization therapies are not routinely used due to the high risk of anaphylactic shock, especially in children. Subcutaneous methods of desensitization have been shown to cause significant side effects. Clinical trials have been performed using oral immunotherapy, which consists in feeding small amounts of the offending allergen to the patient. While some of these trials have shown a desensitization effect, these therapies have been shown to trigger a high proportion of severe systemic reactions in certain cases, and we believe that this has limited their pharmaceutical development in the past.

Moreover, with current desensitization techniques, the achieved immunity may be short-lived; many patients are not able to tolerate the allergen permanently. A therapeutic approach that promotes tolerization to the allergen would be of particular clinical and societal benefit.

***Food and Pediatric Allergies are a High Unmet Clinical Need***

According to a paper published by the AAAAI, approximately 3% to 5% of Americans suffer from food allergies, with a number of recent studies suggesting that nearly six million or approximately 8% of children have some type of food allergy. Food allergies, in particular, can lead to extremely dangerous reactions and often lead to anaphylactic shock. According to a paper published in the Immunology and Allergy Clinics of North America, food, mainly peanut allergies, are responsible for 150 to 200 deaths every year in the United States. The U.S. Centers for Disease Control and Prevention reported that food allergies result in more than 300,000 ambulatory-care visits per year among children under the age of 18. Every three minutes a food allergy reaction sends someone to the emergency department, which is about 200,000 emergency department visits per year, and every six minutes the reaction is one of anaphylaxis. A recent U.S. study indicates an increase of 350% in the number of hospitalizations of children below age 18 for diagnosis of a food allergy for the period from 2004 to 2006 as compared to the period from 1998 to 2000. According to a paper published in the Immunology and Allergy Clinics of North America, the majority of fatal anaphylactic reactions in patients are caused by peanut allergy.

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

Recent studies suggest that patients with food allergies are especially at risk for experiencing significant disruption to their daily life. Food allergies are not only a physical disability; they are often associated with psychological traumas, including fear of eating, antisocial behavior and anxiety. In the case of pediatric patients, food allergies also have a significant impact on their caretakers. A recent study suggests that the quality of life in children with peanut allergy is more impaired than in children with insulin-dependent diabetes mellitus.

*There Are No Approved Treatments Suitable for Food Allergies*

There are currently no approved medical therapies to treat food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important and the most common measures to prevent serious health consequences. However, strict avoidance of food allergen is very difficult to achieve, especially for children. Some foods can contain hidden traces of allergens, labeling is often deceptive and contamination of allergen-free foods occurs regularly. For example, according to a paper published in the Journal of Allergy and Clinical Immunology, or JACI, it is estimated that accidental exposure to peanuts in peanut allergic patients occurs once every three to five years and the annual incidence of accidental ingestion is between 15% and 40%.

*Treating Allergies Early in Life Can Modify the Disease, However, No Treatments Currently Exist for Young Children*

Recent scientific studies suggest that treating allergies early in life could prevent disease progression or the development of polyallergies. A study of children desensitized to pollen and monitored for five years demonstrated that treating pollen allergy reduced the development of asthma. This early intervention, when the immune system is not mature, is referred to as the “window of opportunity.” Thus, research suggests that addressing allergies during this time in life is likely of critical clinical importance.

However, current techniques are poorly adapted to treating young allergy patients:

- Injections are not well-tolerated and must be performed under strict medical supervision; and
- Sublingual methods, developed to encourage home administration, are generally not suitable for young children who are unable to keep the product in contact with the oral mucosa long enough for its use to be effective (a minimum of two minutes before being swallowed). In addition, sublingual administration in children is sometimes poorly tolerated. In the case of tablets, the risk of aspiration also exists. Due to these safety concerns, existing techniques are limited to children who are at least six years old. Given these limitations, it has been difficult to commercialize large-scale desensitization efforts for young children, even if medical research suggests that early allergy treatment during the “window of opportunity” is the best prophylactic and therapeutic management of the disease.

In December 2016, the National Institute of Allergy and Infectious Diseases, or NIAID, a division of the National Institutes of Health, released updated clinical guidelines to aid health care providers in early introduction of peanut-containing foods to infants with the goal of possibly preventing the development of peanut allergy in patients at high-risk of developing peanut allergy. The new Addendum Guidelines for the Prevention of Peanut Allergy supplement the "Guidelines for the Diagnosis and Management of Food Allergy in the United States," which were previously introduced by NIAID in December 2010. Development of the Addendum Guidelines was prompted by emerging data suggesting that peanut allergy may be prevented by early introduction of peanut-containing foods. However, the latest findings are part of a complicated and evolving global allergy landscape, and early introduction of peanut-containing foods is an effort to prevent, rather than treat, peanut allergy. The Addendum Guidelines categorize children by risk of developing a peanut allergy. The Addendum Guidelines recommend that high-risk infants that have already been diagnosed with severe eczema, egg allergy or both should have peanut-containing foods introduced into the diet as early as four to six months of age to reduce the risk of developing peanut allergy. Further, the Addendum Guidelines suggest that infants with mild to moderate eczema may have peanut-containing foods introduced into their diets around six months of age to reduce the risk of developing peanut allergy, and low-risk infants without eczema or any food allergy may introduce peanut-containing foods freely into their diets. The Addendum Guidelines recommend that high-risk infants have an evaluation by an allergy specialist, and that patients diagnosed with a peanut allergy should not be introduced to peanut-containing foods due to the risk of anaphylactic reactions and death. It is uncertain what effect the Addendum Guidelines will have on the development of peanut allergy in children or if it will decrease the prevalence of peanut allergy in the United States.

*There is an Urgent Need for a Safe, Effective and Convenient Treatment for Food Allergic Patients*

For all these reasons, food allergic patients, especially young children, their caregivers and their clinicians have long sought a safe, effective and convenient treatment. It is well understood that desensitization would be a desirable therapeutic approach as long as the procedure limits serious side effects, is convenient to administer and is effective. In particular, a therapeutic approach that promotes a long-term therapeutic effect would be most desirable. To date, no such technique has been developed and approved.

**Our Solution: Epicutaneous Immunotherapy (EPIT®) Using Our Viaskin® Technology Platform**

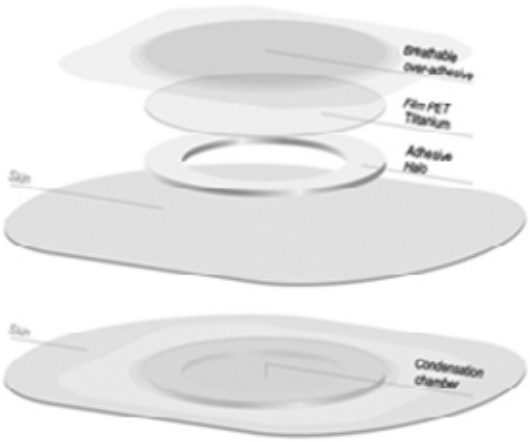
Over the last decade, we have developed an innovative immunotherapy technology platform, with the potential for sustained therapeutic effect, by delivering biologically active compounds, including antigens, via intact skin. This technology platform, which we call Viaskin®, is based on an electrostatic patch, which administers the antigen directly on the skin. Once administered, the antigen is concentrated in the superficial layers of the skin, where it activates the immune system by specifically targeting the Langerhans cells, without passage of the antigen into the bloodstream. We refer to this novel approach to immunotherapy as epicutaneous immunotherapy, or EPIT®. Based on our trials and research, we believe that EPIT® has the potential to provide all of the intended benefits of a disease-modifying treatment in allergy, while avoiding severe or life-threatening allergic reactions.

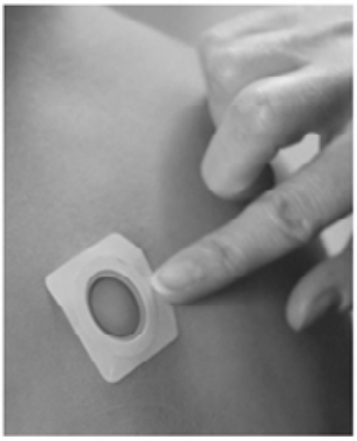
***Viaskin®—The First Epicutaneous Immunotherapy Product Candidate***

Three important characteristics of our Viaskin® technology platform contribute to its potential safety and efficacy:

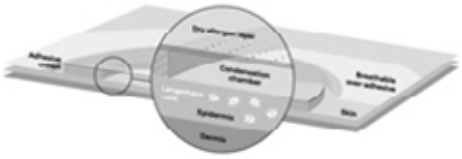
- The Viaskin® patch contains the antigen in dry form, which allows it to retain its chemical properties optimally.
- The Viaskin® patch creates a condensation chamber with the skin. This increases the hydration of the skin and solubilizes the antigen, which allows it to penetrate the upper layers of the epidermis. Here, the antigen is close to tolerogenic, antigen-presenting cells in the body called the Langerhans cells.
- The Viaskin® patch delivers the antigen directly to the Langerhans cells, but not into the bloodstream, thereby aiming to avoid systemic allergic reactions. This mechanism of action leads to the potential safety of Viaskin®, which has been observed in multiple clinical trials in over 1,000 patients.

Below is a diagram reflecting the primary components of the Viaskin® patch:

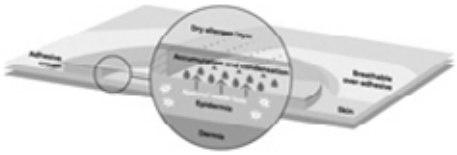


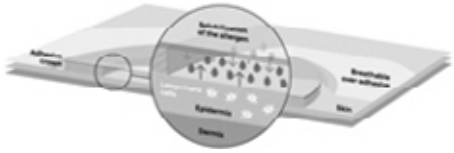
The key elements of the Viaskin® patch mechanism of action are the following:



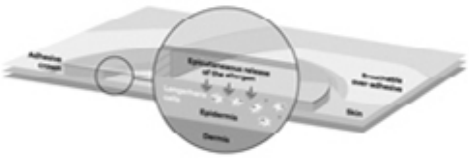
Containing a dry layer of allergen in its center, the patch is positioned on intact skin, without prior preparation.



The condensation chamber formed between the skin and the center of the patch creates hyperhydration of the skin and an accumulation of water.



The accumulation of water solubilizes the allergen. Due to this condensation chamber, the epidermis becomes more permeable allowing passage of the allergen into the epidermis.



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

***Viaskin®—Targeting the Unique Immunological Properties of the Skin***

Viaskin®'s effect on the immune system has been the subject of numerous scientific analyses and publications, which have been featured in major medical journals and allergology conferences. These epigenetic and mechanistic studies have helped us characterize the Viaskin®'s novel mechanism of action.

Our mechanism of action is unique and differentiated as it targets specific epidermal dendritic cells, called Langerhans cells, which capture the antigen and migrate to the lymph node in order to activate the immune system without passage of the antigen into the bloodstream. After the antigen has been presented to the T cells in the lymph node, it activates the Tregs, the main factor in the down-regulation of Th2 response with little influence in Th1 expression, thus rebalancing the immune response.

Th2 cells are thought to play a role in allergic responses because allergies are known to be Th2 dominant conditions. An elevated Th2 response is ultimately responsible for the production of IgE, which can cause inflammation and trigger allergic reactions. Conversely, a normal, or non-allergic, immune response to an allergen is usually characterized by a well-balanced Th1/Th2 response.

We believe that EPIT® can rebalance the immune reaction by decreasing, or down-regulating, the Th2 response to allergens, keeping Th1 and Th2 balanced and thus promoting long-term tolerance toward future allergen exposure. The first documentation of this mechanistic feature of our Viaskin® patch in humans was presented at the 2016 AAAAI Annual Meeting in Los Angeles, California.

***Viaskin®—Compelling Clinical Benefits***

We believe that our innovative approach to EPIT® has the potential to offer compelling clinical benefits to patients suffering from severe allergies:

- Our Epicutaneous Approach Targeting Langerhans Cells has the Potential to Induce an Immune Reaction with a Highly Tolerogenic Profile: By delivering the allergen directly to the lymph node through the Langerhans cells, EPIT® activates specific Tregs that can down-regulate the Th2-oriented reaction to the allergen. The absence of passage of allergens into the bloodstream explains the potential safety while the activity in the lymph node explains the potential efficacy of EPIT®.
- Our Viaskin® Patch Enables Continuous Antigen Exposure which has the Potential to Promote Sustained Tolerization: The Viaskin® patch contains allergen protein in its original antigenic state, which allows the skin to be continuously exposed to the allergen over time. We believe this promotes a long-term, sustained therapeutic effect.
- The Safety Profile and Ease of Use of Viaskin® May Allow the Treatment of Allergies Very Early in Life: Because of its ease-of-use and observed safety profile, we believe our Viaskin® technology will allow for the treatment of all patients suffering from severe allergies, including young children, limiting the risk of treatment-related anaphylaxis. As a result, we believe our approach will permit early treatment of allergies in children during the "window of opportunity" which could prevent disease progression in these patients or the development of polyallergies.

We believe Viaskin®'s ability to induce epicutaneous immunological responses can also potentially be applied to other therapeutic areas, such as vaccination and treatment of inflammatory and autoimmune diseases.

**Our Product Candidates**

Our lead product candidate, Viaskin® Peanut, is being developed for the treatment of peanut allergy in children, adolescents and adults. We completed a Phase III development program for Viaskin® Peanut 250 µg in peanut allergic children four to 11 years of age. In December 2015, we initiated PEPITES, a randomized, placebo-controlled pivotal Phase III trial investigating the safety and efficacy of Viaskin® Peanut 250 µg in 356 patients after 12 months of treatment. In November 2016, we initiated REALISE, a Phase III trial designed to generate safety data after six months of blinded treatment, as well as to evaluate the use of Viaskin® Peanut 250 µg in routine clinical practice. Patients in PEPITES were eligible to enroll in PEOPLE (*Open-Label Follow-Up Study of the PEPITES Study to Evaluate the Long-term Efficacy and Safety of Viaskin® Peanut*), a long-term, open-label extension trial of

Viaskin® Peanut 250 µg. In the PEOPLE trial, patients who were randomized and received active treatment during PEPITES will receive Viaskin® Peanut 250 µg for two additional years, while patients who received placebo during PEPITES will be treated with Viaskin® Peanut 250 µg for three years. We announced the topline results from PEPITES and REALISE in October and November 2017, respectively.

The results from PEPITES and REALISE will form the basis for our planned regulatory submissions in the United States, Europe and other countries for the use of Viaskin® Peanut in this patient population. In February 2018, we announced that the FDA agreed that the available efficacy and safety data for Viaskin® Peanut supports the submission of a BLA for the treatment of peanut allergy in children four to 11 years of age.

In October 2018, we announced the submission of a BLA to the FDA for Viaskin® Peanut for the treatment of peanut allergy in children four to 11 years of age. In December 2018, we voluntarily withdrew our BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data needs on manufacturing procedures and quality controls. In February 2019, we announced that based on the progress in addressing the FDA's guidance, we expect to submit our BLA for Viaskin® Peanut in the third quarter of 2019.

We are also developing Viaskin® Peanut for the treatment of peanut allergy in toddlers one to three years of age. In August 2017, we initiated the EPIT® in Toddlers with Peanut Allergy, or EPITOPE, a Phase III clinical trial assessing the safety and efficacy of Viaskin® Peanut for the treatment of peanut allergic patients one to three years of age. In September 2018, we announced that the independent DSMB completed its planned safety review of Part A of the EPITOPE trial. The DSMB did not identify any safety concerns for patients enrolled in Part A of the trial and recommended that the trial continue as planned with the 250 µg dose selected for investigation in Part B. In October 2018, we announced the initiation of Part B of EPITOPE. We expect to enroll approximately 400 toddlers for Part B in the United States, Europe, Australia and Canada. Patients in the EPITOPE trial were eligible to enroll in EPOPEX (*EPITOPE Open-Label Extension Study to Evaluate the Long-Term Clinical Benefit and Safety of Viaskin® Peanut in Peanut-Allergic Children*), a long-term, open-label extension trial of Viaskin® Peanut 250 µg in toddlers. In the EPOPEX trial, patients who were randomized and received active treatment during EPITOPE will receive Viaskin® Peanut 250 µg for two additional years, while patients who received placebo during EPITOPE will be treated with Viaskin® Peanut 250 µg for three years.

Our second product candidate, Viaskin® Milk, is being developed for children and adolescents for the treatment of IgE mediated CMPA. Proof-of-concept data from a pilot clinical trial of Viaskin® Milk was published in JACI in 2010. In November 2014, we initiated our 198-subject, multi-center, double-blind, placebo-controlled, randomized Phase I/II dose-finding MILES clinical trial evaluating the safety and efficacy of Viaskin® Milk in children two to 11 years of age and adolescents 12 to 17 years of age with IgE mediated CMPA. Completion of Part A (Phase I) occurred in June 2015. In February 2018, we reported results from this dose-finding trial. Following analyses of the data, the 300 µg dose was identified as the dose with the greatest observed clinical activity for children (ITT, p=0.042). We believe these results support further advancement of the Viaskin® Milk program, and we intend to discuss findings with regulatory authorities to determine the design of future studies.

We are also developing a third product candidate, Viaskin® Egg, for the treatment of hen's egg allergy. In the first half of 2015, we began pre-clinical work for this product candidate with the goal of initiating a clinical program if these studies are successful. Preclinical development is currently ongoing.

To support our pipeline innovation strategy, we have commenced a number of proof-of-concept trials in the field of inflammatory and autoimmune diseases. In November 2015, Dr. Jonathan Spergel from CHOP initiated an investigator-sponsored multi-center, double-blind, placebo-controlled, randomized trial to assess the safety and efficacy of Viaskin® Milk in pediatric patient populations with milk-induced EoE. CHOP presented finding from this 20-patient trial in December 2018 and February 2019. A reduction in eosinophil counts was observed in this initial data set, showing a possible connection between the skin and the gastrointestinal tract. We also initiated our first human proof-of-concept trial in the field of boosting vaccination in September 2016 in collaboration with HUG and BioNet. We, in collaboration with HUG and BioNet, designed a Phase I trial to study the ability of Viaskin® rPT in the reactivation of immunity against Bordetella pertussis in 60 healthy adults. The primary endpoint of the study was the incidence of treatment-emergent adverse events, or TEAEs, related to the application of Viaskin® rPT and the secondary objectives assessed humoral responses compared to placebo In November 2016, we announced the completion of dosing in the first cohort and the DSMB recommendation that the study continue with dosing in the

second patient cohort. We announced the results of this trial in March 2017. In September 2018, we presented data from two additional cohorts, showing that following skin preparation with an epidermal laser, anti-PT booster responses elicited by Viaskin®-PT were comparable to those elicited by Boostrix® dTpa, an injectable approved booster vaccine.

We are also exploring the use of the Viaskin® technology platform in the development of diagnostic tools for food allergies. In May 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopy patch test for the diagnosis of CMPA in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally.

***Viaskin® Peanut***

*Background*

Peanut allergy is one of the most common food allergies, and can cause severe, potentially fatal, allergic reactions, including anaphylaxis. Strict avoidance of peanut is necessary as even trace amounts of peanut can cause severe allergic reactions. According to recent studies, food allergies, mainly to peanut, are responsible for 150 to 200 deaths every year in the United States and about 200,000 emergency room visits. While anaphylactic shock is the most severe allergic reaction to peanuts, many patients also suffer from a poor quality of life. Peanut allergies have lifelong effects and are often associated with psychological traumas, including fear of eating, antisocial behavior and anxiety.

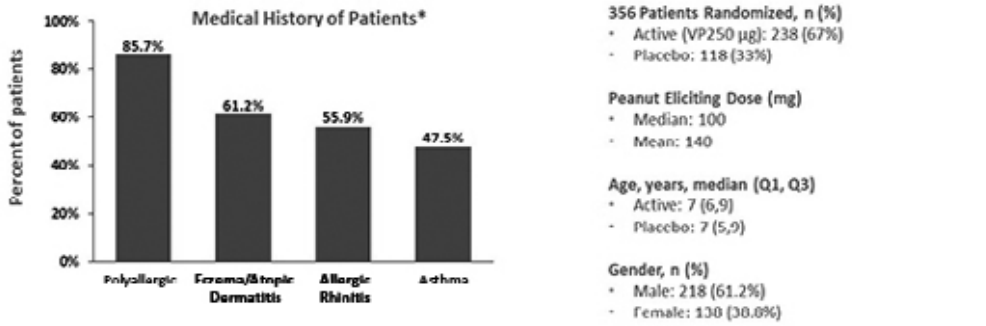
Allergy to peanuts appears to be on the rise and its prevalence has increased in the past 10 years. According to an article published in JACI, a recent survey in the United States indicated that approximately 1% of the U.S. population, or more than three million people, are allergic to peanuts and/or nuts. Two recent studies conducted in the United States and the United Kingdom show that peanut allergy has doubled in five years in children below age five. A study funded by Food Allergy Research and Education, Inc., or FARE, indicates that the number of children in the United States with peanut allergy more than tripled between 1997 and 2008. Although some patients outgrow their peanut allergies, research indicates that only about 20% of individuals with peanut allergy outgrow it during a lifetime.

*Phase III Clinical Program Ages Four to 11 — PEPITES and REALISE*

*PEPITES (Peanut EPIT® Efficacy and Safety Study)*

In December 2015, we initiated a pivotal Phase III trial designed to evaluate the safety and efficacy of Viaskin® Peanut 250 µg in children four to 11 years of age suffering from peanut allergy. PEPITES was a global, randomized 2:1, double-blind, placebo-controlled Phase III trial, in which pediatric peanut allergic patients were treated with Viaskin® Peanut 250 µg or placebo for 12 months. During the trial, patients' sensitivity to peanut protein was assessed using a double-blind, placebo-controlled food challenge, or DBPCFC, at baseline. The DBPCFC was halted once the subject exhibited an objective symptom, as described on a pre-specified scale, thus establishing a subject's peanut reactivity level, which is labeled as the patient's eliciting dose, or ED. As in VIPES, patients received a daily application of Viaskin® Peanut or placebo over a 12-month treatment period. Each patch was to be applied for 24 hours on the patient's back.

PEPITES randomized 356 peanut allergic patients in 31 centers across North America, including Canada and the United States, Europe and Australia. The patient population included a high percentage of subjects who exhibited additional allergic conditions. We established baseline peanut tolerance levels by measuring the peanut eliciting dose at which patients began to exhibit allergy symptoms, thus establishing the reactive baseline dose. The median baseline reactive dose in PEPITES was 100 mg.

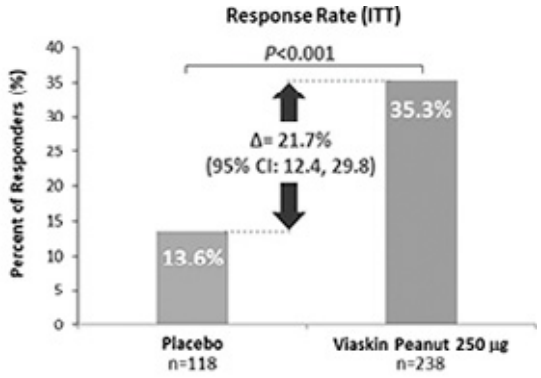



*Medical History displayed as summary of the trial population. VP250 µg patients: polyallergic n=205 (86.1%), eczema/atopic dermatitis n=139 (58.4%), allergic rhinitis n=132 (55.5%), asthma n=117 (49.2%); placebo patients: polyallergic n=100 (84.7%), eczema/atopic dermatitis n=79 (66.9%), allergic rhinitis n=67 (56.8%), asthma n=52 (44.1%).
Q=quartile; VP250=Viaskin Peanut 250 µg.
1. Fleischer DM, et al. JAMA. 2019. doi:10.1001/jama.2019.1113.

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

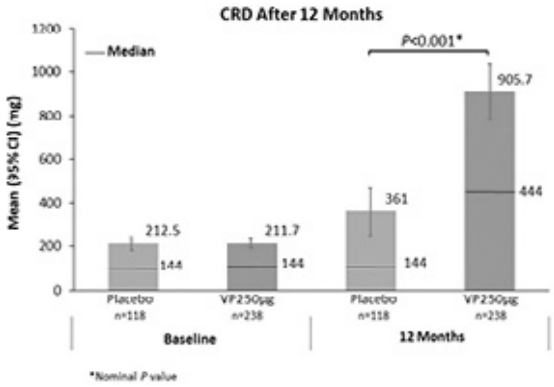
*Results of PEPITES Trial*

In October 2017, we announced topline results from PEPITES, in which we observed a statistically significant response with a favorable tolerability profile, with 35.3% of patients responding to Viaskin® Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates = 21.7%; p=0.00001; 95% CI = 12.4% - 29.8%). However, the primary endpoint, which evaluates the 95% CI in the difference in response rates between the active and placebo arms, did not reach the 15% lower bound of the CI that was proposed in the study's Statistical Analysis Plan submitted to the FDA. We presented these topline results at the 2018 AAAAI/WAO Joint Congress in Orlando, Florida in March 2018. Detailed results were published in The Journal of the American Medical Association in February 2019.



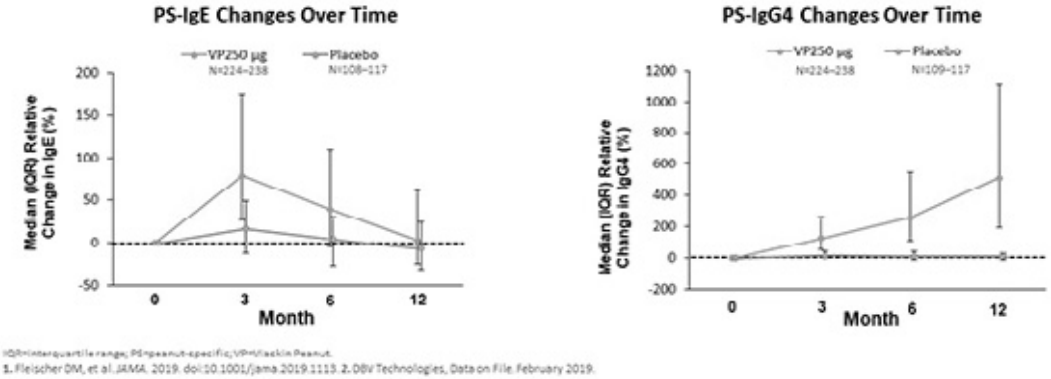

CI=confidence interval; ITT=intention-to-treat.
1. Fleischer DM, et al. JAMA. 2019. doi:10.1001/jama.2019.1113.

With respect to CRD, a key secondary endpoint which measures threshold reactivity during the DBPCFC, we observed that at month 12, patients treated with Viaskin® Peanut 250 µg and placebo reached a mean CRD of 906 mg (median 444 mg) and 361 mg (median 144 mg) of peanut protein, respectively. Mean CRD at baseline was 211.7 mg (median 144 mg) in the Viaskin® Peanut arm and 212.5 mg (median 144 mg) in the placebo arm. An increase in the CRD was observed between Viaskin® Peanut and placebo (nominal p-value < 0.001).



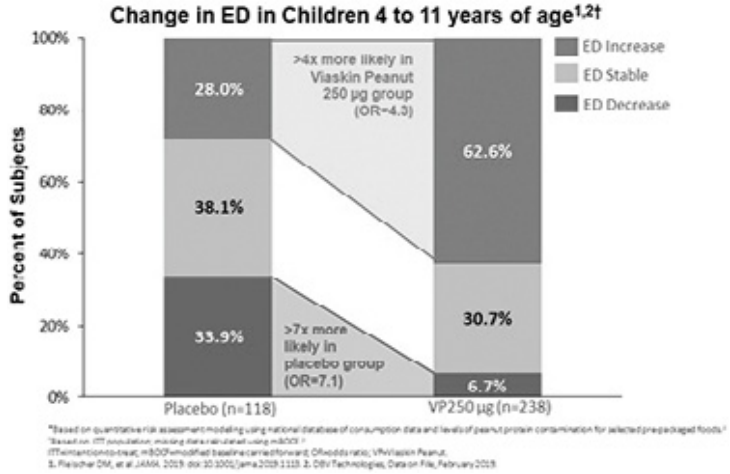

Exploratory analyses showed that changes in peanut-specific biomarkers, including immunoglobulin E (IgE) and immunoglobulin G4 (IgG4), support the immunomodulatory effect with Viaskin® Peanut [Figure 1]. The median observed increase from baseline in peanut-specific IgE was greater in the Viaskin® Peanut group vs placebo group, respectively, at month 3 (70.1 kilounits of antibody per liter (kUA/L) vs 9.8 kUA/L) and month 6 (27.4 kUA/L vs 1.32 kUA/L). However, at month 12, peanut-specific IgE were observed to return to near baseline in both groups (1.1 kUA/L vs -1.1 kUA/L). Median peanut-specific IgG4 were observed to increase over time in the Viaskin® Peanut group (change from baseline at month 3: 0.81 mg/L; month 6: 1.79 mg/L; month 12: 3.27 mg/L), while levels remained unchanged from baseline in the placebo group. The change from baseline in peanut-specific IgG4 was greater at all time points with Viaskin® Peanut vs placebo, and the groups were observerd to be highly distinguished by this marker, given a flat trend in the placebo arm.

**Figure 1: PEPITES Immunological Responses**




IQR=interquartile range; PS=peanut-specific; VP=Viaskin Peanut.
1. Fleischer DM, et al. JAMA. 2019. doi:10.1001/jama.2019.1113. 2. DBV Technologies, Data on File. February 2019.

In a post-hoc analysis, the majority of patients on Viaskin® Peanut exhibited an increased ED compared to the placebo group (62.6% in active vs. 28% in placebo) at 12 months. An additional post-hoc analysis showed that 53.1% of patients treated with Viaskin® Peanut increased their baseline ED from ≤100 mg to ≥300 mg, compared to 19% in the placebo group. Based on quantitative risk modeling from Baumert et al, this improvement in ED is predicted to reduce the risk of an allergic reaction due to accidental exposure by over 95%.




*Based on quantitative risk assessment modeling using national database of consumption data and levels of peanut protein contamination for selected prepackaged foods.[1]
†Based on ITT population, missing data calculated using mBOCF.[1]
ITT=intent-to-treat; mBOCF=modified baseline carried forward; OR=odds ratio; VP=Viaskin Peanut.
1. Fleischer DM, et al. JAMA. 2019. doi:10.1001/jama.2019.1113. 2. DBV Technologies, Data on File, February 2019.

A favorable safety and tolerability profile was observed with Viaskin® Peanut. Treatment adherence was high (98.5%), and similar discontinuation rates between treatment groups were reported, with 89.9% of patients completing the trial. There was a low discontinuation rate due to treatment-emergent adverse events (TEAEs) (1.7%), and the overall rate of TEAEs, regardless of relatedness to the treatment, was comparable between treatment and placebo groups, at 95.4% and 89.0%, respectively. The most commonly reported TEAEs were mild to moderate application-site reactions that decreased after month 1 in both frequency and severity. There were no treatment-related gastrointestinal adverse events or cases of eosinophilic esophagitis in this trial.

There were no cases of severe anaphylaxis in the trial. Serious adverse events (SAEs) were balanced between the Viaskin® Peanut and placebo group, at 4.2% vs. 5.1%, respectively. Four SAEs reported in three Viaskin® Peanut patients (1.3%) were determined by the investigator as possibly or probably related to treatment. A low rate of treatment-related epinephrine use was reported (2.9% treatment group vs. 0.8% placebo group). Ten cases in eight Viaskin® Peanut patients (3.4%) of possibly or probably treatment-related anaphylaxis occurred, and all were classified as mild or moderate without evidence of cardiovascular, neurologic, or respiratory compromise. Six of these ten cases were treated with epinephrine, and five of the eight patients continued on Viaskin® Peanut in the trial.

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

*REALISE (REAL Life Use and Safety of EPIT®)*

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

No DBPCFCs were required for entry or during the trial. Patients in the study were selected based on a well-documented medical history of IgE-mediated reactions to peanut, including children with a history of severe anaphylaxis. The primary endpoint of the study is safety as measured by adverse events, treatment-emergent adverse events and serious adverse events after six months of blinded treatment. Secondary endpoints include evolution of peanut-specific serological markers over time, including IgE, immunoglobulin G and skin prick test wheal. Exploratory criteria will also include scores from patients' Food Allergy Quality of Life Questionnaire, or FAQLQ, and the Food Allergy Independent Measure, FAIM.

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

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

*Results of REALISE Trial*

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

*Phase III Clinical Trial Ages One to Three—EPITOPE*

*EPITOPE (EPIT® in Toddlers with Peanut Allergy)*

In August 2017, we initiated EPITOPE, a two-part, pivotal, double-blind, placebo-controlled Phase III trial designed to evaluate the safety and efficacy of Viaskin® Peanut in children one to three years of age suffering from peanut allergy. Part A of the trial assessed the safety of two doses of Viaskin® Peanut, 100 µg and 250 µg, in 51 patients for three months. Based on the results from Part A, we are studying the maximum-tolerated dose in Part B, which is expected to enroll approximately 350 additional patients to evaluate the safety and efficacy of the identified dose versus placebo for 12 months.

The primary efficacy endpoint of the trial is based on a responder analysis after 12 months of treatment of Viaskin® Peanut. For patients with a baseline peanut protein ED equal to or less than 10 mg, a responder is defined as a patient with a peanut protein ED equal to or greater than 300 mg of peanut protein after 12 months of treatment. For patients with a baseline ED greater than 10 mg, a responder is defined as a patient with a peanut protein eliciting dose equal to or greater than 1,000 mg of peanut protein after 12 months of treatment. The primary analysis evaluating the difference between Viaskin® Peanut 250 µg and placebo is defined by reaching a lower bound of the two-sided 95% confidence interval (CI) of ≥15%.

In September 2018, we announced that the independent DSMB completed its planned safety review of Part A of EPITOPE and did not identify any safety concerns for patients enrolled in Part A of the trial, recommending that the trial continue as planned with the 250 µg dose selected for investigation in Part B. In October 2018, we announced the initiation of Part B of EPITOPE. We expect to enroll approximately 400 toddlers for Part B in the United States, Europe, Australia and Canada.

Patients in EPITOPE were eligible to enroll in EPOPEX (*EPITOPE Open-Label Extension Study to Evaluate the Long-Term Clinical Benefit and Safety of Viaskin® Peanut in Peanut-Allergic Children*), a long-term, open-label extension trial of Viaskin® Peanut 250 µg in toddlers. In the EPOPEX trial, patients who were randomized and received active treatment during EPITOPE will receive Viaskin® Peanut 250 µg for two additional years, while patients who received placebo during EPITOPE will be treated with Viaskin® Peanut 250 µg for three years.

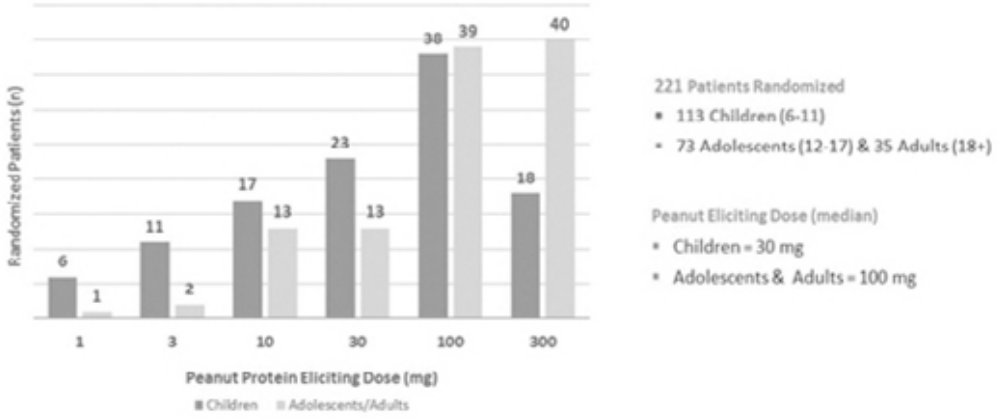
*Phase IIb Clinical Trials—VIPES and OLFUS-VIPES*

*VIPES (Viaskin® Peanut's Efficacy and Safety)*

In August 2012, we initiated VIPES, a double-blind, placebo-controlled, multi-center Phase IIb clinical trial of Viaskin® Peanut in 221 peanut allergic patients with a well-documented medical history of systemic reactions after ingestion of peanut. Patients completed their last food challenge visits after twelve months of treatment.

The VIPES trial was a multi-center clinical trial conducted at 22 sites in North America and Europe. In the trial, 221 peanut allergic patients were randomized into four treatment arms to evaluate three doses of Viaskin® Peanut, specifically 50 µg, 100 µg and 250 µg peanut protein, compared to placebo. The trial was prospectively organized across the three dose levels with two patient strata, composed of three different patient age groups: children (113 patients, ages six to 11) for the first stratum and adolescents (73 patients, ages 12 to 17) plus adults (35 patients, ages 18 to 55) for the other stratum. Each patient underwent two DBPCFCs: one at initial screening and one at 12 months after initiation of treatment. The challenge was halted once the subject exhibited an objective symptom, thus establishing a subject's ED. Patients in VIPES received a daily application of the Viaskin® Peanut patch over a 12-month treatment period. Each patch was applied for 24 hours, either on the upper arm for adults (ages 18 to 55) and adolescents (ages 12 to 17) or on the back of children (ages six to 11).

Baseline peanut tolerance levels were established by measuring the peanut eliciting dose at which patients began to exhibit allergy symptoms, thus establishing the reactive baseline dose. The median baseline reactive dose in VIPES was 30 mg for children and 100 mg for adolescents and adults. The distribution of patients' baseline reactive dose is summarized in the graph below.




The primary efficacy endpoint in the trial was the percentage of treatment responders for each active treatment compared to placebo. Trial responders were defined as patients who, after 12 months of treatment with Viaskin® Peanut and using a DBPCFC, started to react at a dose of peanut protein equal to or greater than 1,000 mg, or at least a 10-fold increase in the eliciting dose of peanut protein compared to baseline. As a secondary efficacy endpoint, CRD was also used to establish the total quantity of peanut protein triggered patient reactions at month 12 versus placebo. Serological markers were also measured as additional secondary endpoints at baseline, three, six and 12 months in order to characterize the immunological changes observed in patients.

The principal coordinating investigator for VIPES in North America is Dr. Hugh Sampson, M.D., Chief of the Division of Allergy & Immunology in the Department of Pediatrics, Director of the Jaffe Food Allergy Institute, and Dean of Translational Biomedical Science at The Mount Sinai Medical Center in New York, United States. Dr. Sampson joined us in June 2015 and was appointed as our Chief Scientific Officer in November 2015.

The principal coordinating investigator for VIPES in Europe is Christophe Dupont, M.D., Ph.D., Head of the Pediatric-Gastroenterology Ambulatory Department at the Necker Hospital, or AP-HP. Dr. Dupont is a member of the European Society for Pediatric Gastroenterology, Hepatology and Nutrition and of the Committee of Nutrition of the French Pediatric Society. Dr. Dupont is also the Chairman of our Scientific Advisory Board.

*Results of VIPES Trial*

In September 2014, we announced topline results for the VIPES trial, which was followed by a full study presentation at the 2015 AAAAI Annual Meeting in Houston, Texas, during an oral presentation by Dr. Sampson titled, "Epicutaneous Immunotherapy (EPIT®) is effective and safe to treat Peanut Allergy: a multi-national, double-blind placebo-controlled randomized, phase IIb trial." We discussed additional post-hoc analyses during a company event webcasted following the 2015 AAAAI meeting.

The primary efficacy endpoint was met with Viaskin® 250 µg, with 50.0% responders vs 25.0% with placebo, p=0.01 [Figure 2]. Moreover, children in the Viaskin® 250 µg arm (six-11 years) exhibited 53.6% responders vs 19.4% for placebo, p=0.008 [Figure 3]. In children, the mean CRD showed a Viaskin® Peanut dose-dependent response, with a change from baseline of +61 mg, +471 mg, +570 mg and +1121 mg for the placebo, 50 µg, 100 µg, and 250 µg arms, respectively [Figure 4]. Children's immunological responses were observed to be robust. In the Viaskin® 250 µg arm, peanut-specific IgE exhibited a median increase ≥ 50 kUA/L at 3 months and decreased back to baseline at 12 months; median peanut-specific IgG4 at 12 months increased in a dose-dependent fashion: 1.3, 5.5-, 7.2- and 19.1-fold for each dose arm, respectively [Figure 5].

We are conducting additional analyses on the adolescents and adults age stratum. Due to a high placebo response rate, we believe these results need to be investigated further before determining our Viaskin® Peanut development path in these patient populations [Figure 6]. We intend to refine our development strategy for both peanut allergic adolescents and adults in the next 12 months.

Patient compliance with daily Viaskin® Peanut application was above 97%. The safety profile was confirmed across all active arms with no serious treatment-related adverse events reported or use of epinephrine related to treatment. Three separate Data Safety Monitoring Board, or DSMB, meetings concluded that VIPES did not have any safety concerns. In the trial, there were 20 SAEs, but none related to study drug. Of the 20 Serious Adverse Events, or SAEs, in VIPES, 14 were anaphylaxes during the DBPCFC, three were moderate anaphylaxes after accidental consumption of peanut containing foods outside of clinical trial site, one was a reaction to fish consumption, one respiratory distress case and one psychiatric case. The trial drop-out rate was 6.3%, or 14 patients, which was below the 15% rate initially anticipated. Two of the 14 drop-outs were related to the study drug due to dermatitis, one was due to uncontrolled asthma not related to treatment and the remaining 11 patients were drop-outs due to non-compliance, lost to follow-up or consent withdrawals. Furthermore, local cutaneous reactions, mostly mild and moderate, were observed in the majority of the active groups.

The following figures summarize these results.

**Figure 2: Summary of VIPES Responders**

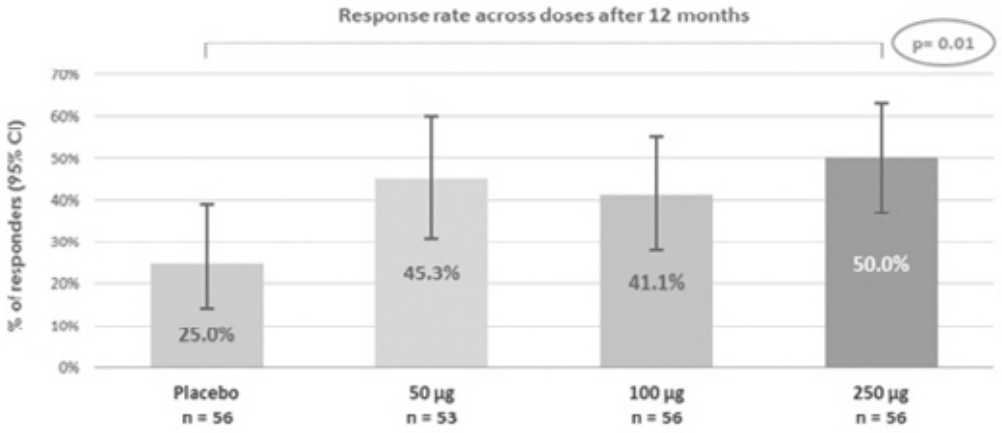



**Figure 3: Summary of VIPES Responders: Children**

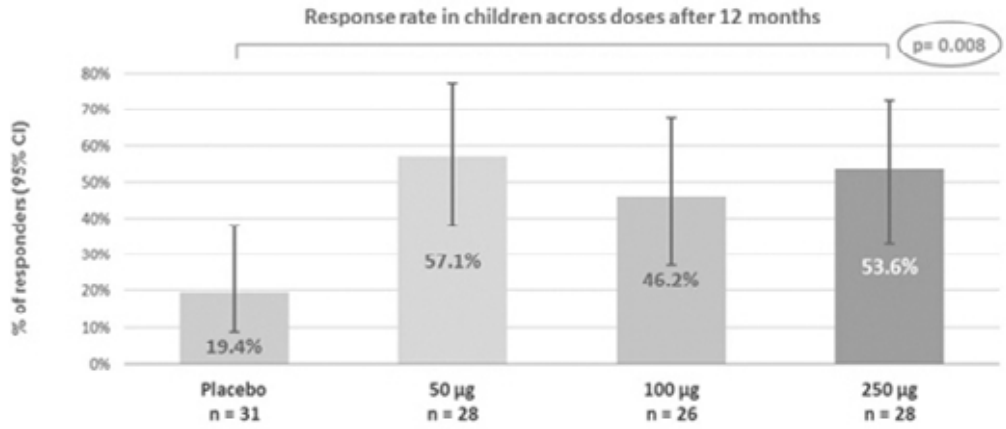


**Figure 4: Summary of CRD Changes from Baseline in Children**

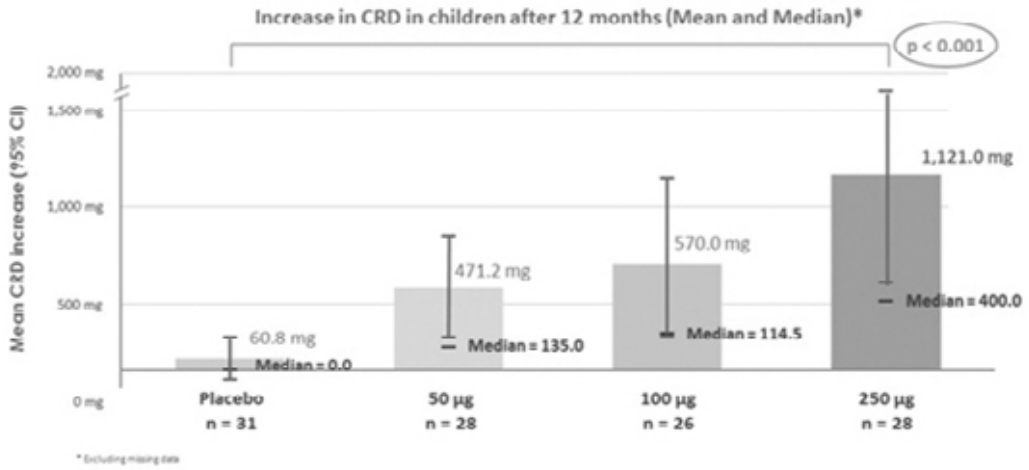



**Figure 5: Summary of Immunological Responses in Children**

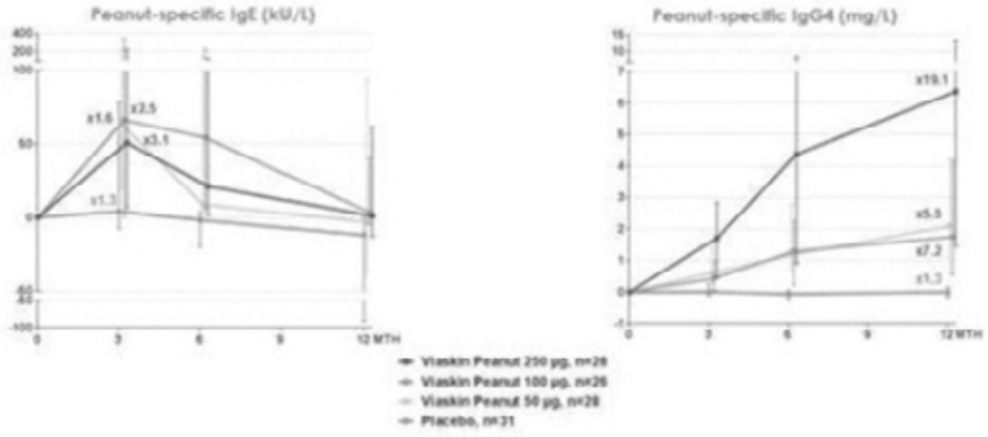
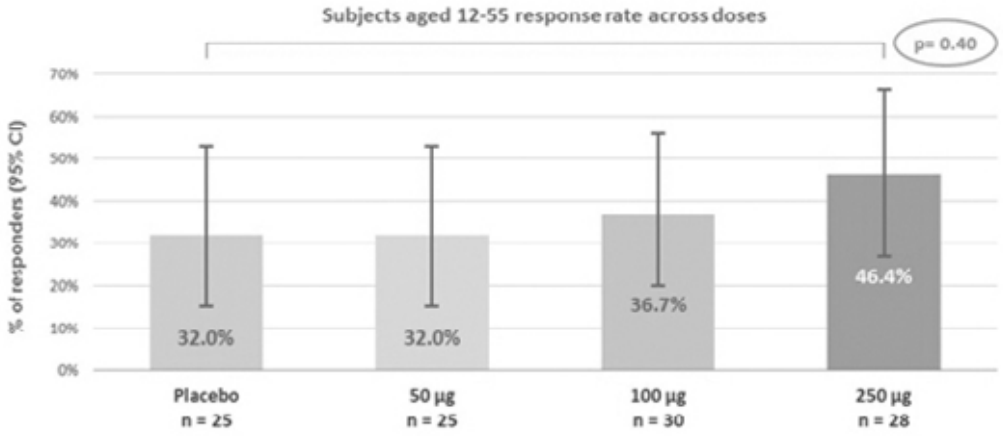


**Figure 6: Summary of VIPES Responders: Adolescents and Adults**




*OLFUS-VIPES (Open-Label Follow-Up Study)*

In September 2013, we initiated an open-label follow-up Phase IIb clinical trial called OLFUS-VIPES to assess the long-term efficacy and safety of Viaskin® Peanut in patients with peanut allergy. OLFUS-VIPES is an extension trial for patients who completed the VIPES double-blind, placebo-controlled clinical trial, during which all patients were under active treatment with Viaskin® Peanut 250 µg. OLFUS-VIPES includes 171 patients at 21 sites in North America and Europe, representing 83% of the patients who completed 12 months of therapy in the VIPES trial. The objective of this trial was to assess the efficacy and safety of Viaskin® Peanut after up to 36 months of epicutaneous immunotherapy in peanut allergic patients, as well as sustained unresponsiveness of patients to peanut protein after cessation of treatment.

*Results of OLFUS-VIPES Trial*

In October 2016, we announced topline results for OLFUS-VIPES, which evaluated the long-term efficacy and safety of Viaskin® Peanut for the treatment of peanut allergic children. The response rate in children (ages six to 11 at entry in VIPES) treated with the 250 µg dose for 36 months was observed to be long-lasting. In this dose cohort, 83% of children were observed to continue responding to treatment during the second year of OLFUS, up from 80% at month 12 of OLFUS and 57% at the OLFUS baseline. The average CRD for this treatment group progressed to 2,454 mg (1,440 mg median) of peanut protein at the completion of OLFUS, from 1,884 mg (1,440 mg median) at month 12 of OLFUS, from 1,068 mg (444 mg median) at the OLFUS baseline, and 84 mg (44 mg median) at baseline during VIPES entry [Figure 7]. Serological markers for this treatment group showed the strengthening of the immunological changes initially observed in VIPES. After 36 months, a median 36.5% decrease from the VIPES baseline value in peanut-specific IgE was observed, while the high median levels IgG4 were maintained at a 473% increase from the VIPES baseline [Figure 8]. Detailed study results were presented at the 2017 AAAAI meeting in Atlanta, Georgia by Dr. Wayne Shreffler during an oral presentation titled, “Efficacy and Safety of Long-Term Epicutaneous Immunotherapy (EPIT®) Treatment of Peanut Allergy with Viaskin® Peanut: Results of the Two-Year Extension of the VIPES Phase IIb Clinical Trial.”

No drug-related epinephrine use or SAEs due to Viaskin® Peanut were reported. The study’s median compliance rate, which was maintained at 95.5%, was also consistent with previously reported results from VIPES and prior observations in OLFUS. Most adverse events were related to application site and were mild to moderate, with decreasing severity and frequency over time.

After 24 additional months of treatment with Viaskin® Peanut, no additional significant clinical response was observed relative to the OLFUS baseline in the adolescents and adults’ treatment group. Response rates consistent with the results observed in VIPES were shown in treatment-naïve adolescents and adults who received 24 months of therapy during OLFUS.

The following figures summarize these results.

**Figure 7: Summary of Responders in OLFUS-VIPES — Children Treated for 36 Months with Viaskin® 250 µg**

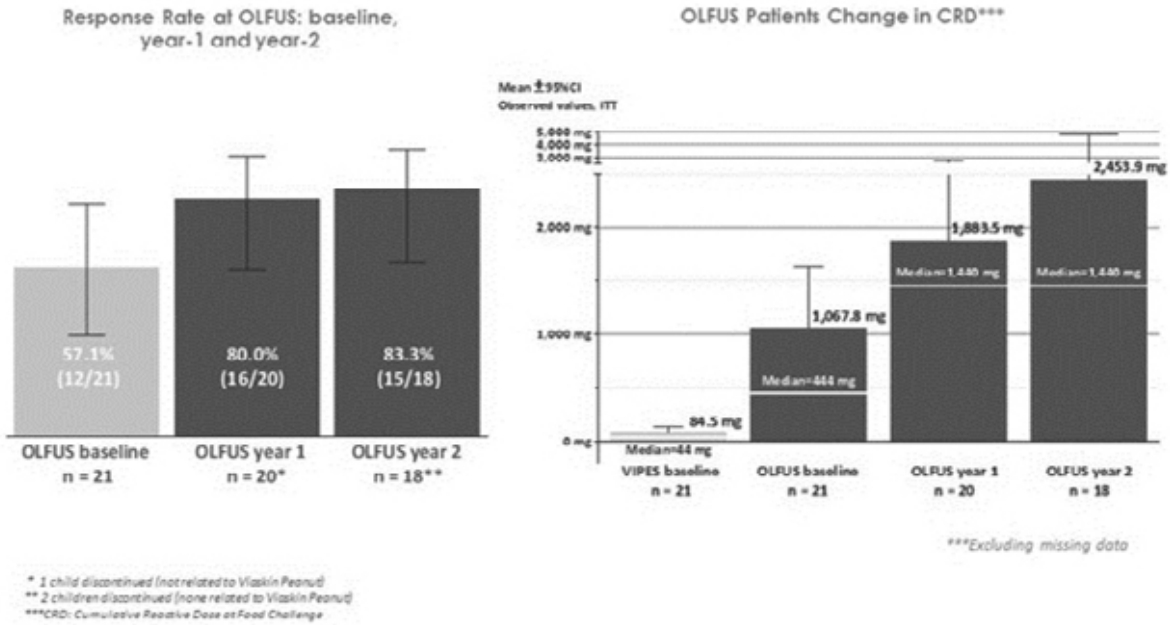
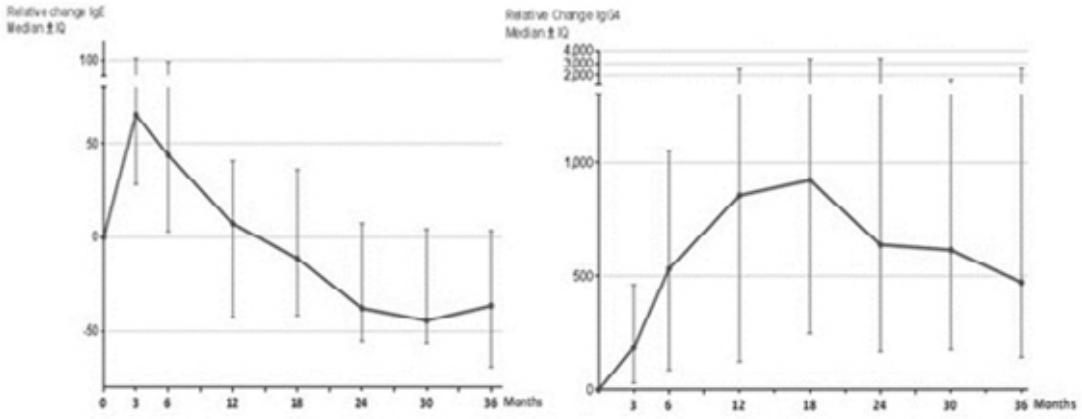



**Figure 8: OLFUS-VIPES Serological Evolution in Children Treated for 36 Months with Viaskin® 250 µg**



*Phase Ib Clinical Trial*

In July 2010, we initiated our first clinical trial of Viaskin® Peanut in the United States, which was a Phase Ib trial to evaluate the safety and tolerability of repeated epicutaneous administration of Viaskin® Peanut in patients allergic to peanuts. Results from this trial were published in February 2016 in JACI. In the trial, which was conducted at five leading centers in the United States, 100 patients (initially adults, followed by adolescents and then children) allergic to peanuts, including 70 with a non-severe allergy and 30 with a severe allergy, were randomized and treated for two weeks with 20 µg to 500 µg of Viaskin® Peanut or with placebo. Patients with a history of severe anaphylactic reactions could be enrolled only after assessment of the safety of Viaskin® Peanut in patients with historical non-severe anaphylaxis. The primary endpoint of this clinical trial was safety, with the primary safety parameters of adverse events, physical examinations, vital signs, lab values, allergic reactions, any skin reactions, local or distant, echo-cardiogram, and Peak Expiratory Flow and spirometry (FEV1). Secondary endpoints included the proportion of patients that experience systemic reactions such as urticaria, asthma and acute dyspnea, change in blood pressure, and digestive symptoms such as vomiting and diarrhea associated with Viaskin® Peanut treatment versus placebo, the proportion of patients requiring treatment for systemic reactions related to Viaskin® Peanut treatment or placebo, and overall adherence to the clinical trial treatment.

In the overall population, the dose of 500 µg of Viaskin® Peanut in adults and adolescents, and the dose of 250 µg of Viaskin® Peanut in children, were each shown to be well-tolerated maximum doses regardless of the administration plan. Importantly, an excellent treatment compliance rate greater than 96% was observed and the intermediate results suggested satisfactory usage safety of Viaskin® Peanut in patients allergic to peanuts. The interim report was communicated to the FDA on December 15, 2011, and we released the complete results of this clinical trial at the EAACI Congress in June 2012.

*Academic Trials*

The lack of cure and approved treatments for food allergies has encouraged researchers and physicians to conduct several observational and mechanistic studies to further their understanding of these diseases. In the United States, for example, the NIAID of the United States National Institutes of Health has substantially increased its support for food allergy research since 2003, including the establishment of CoFAR in 2005.

As such, we have been approached by certain academic and research institutions interested in exploring Viaskin® and EPIT®'s mechanism of action and their impact on patients. In particular, both the AP-HP in France and CoFAR in the United States have initiated clinical trials to assess Viaskin® Peanut's efficacy: ARACHILD and CoFAR6, respectively. While not a sponsor of these trials, we have and will provide the doses of Viaskin® Peanut needed to complete both of these trials.

*CoFAR6 (Consortium for Food Allergy Research 6)*

In October 2013, CoFAR launched a multi-center, randomized, double-blind, placebo-controlled trial to evaluate Viaskin® Peanut in children and adults allergic to peanuts. This trial is sponsored and funded by the NIAID and coordinated by Stacie M. Jones, MD, Professor of Pediatrics, University of Arkansas for Medical Sciences, Arkansas Children's Hospital, Little Rock, Arkansas. The trial is being conducted in five hospitals in the United States and includes 75 patients; 54 children four to 11 years of age and 21 adolescents and adults 12 to 25 years of age. In CoFAR6, patients were randomized 1:1:1 to two doses of Viaskin® Peanut (100 µg and 250 µg) or placebo. The primary outcome measure was the percent of patients desensitized to peanut protein during the peanut protein oral food challenge, or OFC, at week 52. Responders were characterized as patients who successfully passed a 5044 mg OFC or who successfully consumed a dose ten times greater as compared to baseline.

The 52-week CoFAR6 results were highlighted during two oral presentations at the 2016 AAAAI Annual Meeting in Los Angeles, California. Findings from this study were consistent with clinical data trends previously observed in VIPES. In the CoFAR6 trial, Viaskin® Peanut was observed to have a favorable safety and tolerability profile across treatment groups, with no SAEs or epinephrine use related to treatment observed. Treatment adherence was high (97.1%), dropouts were low (8%), and no withdrawals occurred in the 250 µg treatment group. Cohorts treated with both Viaskin® Peanut 100 µg (P=0.005), and Viaskin® Peanut 250 µg (P=0.003) met the primary efficacy endpoint in all populations. The treatment response was enhanced in children four to 11 years of age, and also, with Viaskin® Peanut 250 µg compared to Viaskin® Peanut 100 µg. Based on additional analysis presented separately by us, we observed a greater response in children treated with the 250 µg dose (P=0.001). The CoFAR6 results were published in JACI in October 2016.

CoFAR6 also explored mechanistic features of Viaskin® Peanut. Dr. Cecilia Berin, Associate Professor Pediatrics, Mount Sinai Hospital in New York, New York presented early findings from CoFAR6 at the 2016 AAAAI meeting, which supported Viaskin® Peanut's mechanistic features that have been observed at the preclinical level. Viaskin® Peanut at the 250 µg dose showed a trend of decreased Th2 cell frequency without any increased trends in the Th1 response. In animal models, we have observed that Viaskin®'s unique mechanism of action could rebalance the immune reaction by down-regulating the Th2 response to allergens while keeping Th1 responses balanced.

*ARACHILD*

The ARACHILD trial is a pilot trial conducted in France by the AP-HP. It is a DBPCFC trial to investigate the efficacy and safety of Viaskin® Peanut in peanut allergic patients recruited from six centers. In the trial, 54 patients (35 children (age five to 11) and 19 adolescents (age 12 to 18)), were randomized into two treatment arms to evaluate a single dose of Viaskin® Peanut, specifically 100 µg of peanut protein, compared to placebo. Patients in the placebo arm were crossed over at six months to Viaskin® Peanut without unblinding the trial. Each patient underwent DBPCFCs at months six, 12 and 18 after initiation of treatment. After the initial double-blind six-month treatment period, all patients went through an open-label period of 30 months. The primary endpoint of the trial was the proportion of patients who achieved at least a 10-fold increase in initial reactive dose or CRD greater than 1,000 mg of peanut protein (about four peanuts). The secondary endpoints included significant immunological changes.

In June 2013, AP-HP reported the results from the initial six-month double-blind placebo-controlled phase of the trial and for the first 12 months of the open-label follow-up phase. In the active group (28 patients), six-, 12- and 18-month data showed 7.4%, 20% and 40% of patients, respectively, consuming at least 10 times more peanut protein than tolerated at the beginning of the trial (versus 7.7% in the placebo arm before the crossover to Viaskin® Peanut at month six, then 13% and 19% respectively after the crossover). Net trends of a specific sub-analysis of 19 adolescents (age 12 to 17) showed that despite a positive serological response of IgE, no adolescents qualified as responders at six, 12 and 18 months. In an analysis of 35 children (age five to 11), we observed not only a positive serological response of IgE, but also that an immunological response is characteristic of an acquisition of tolerance leading to a continuous and progressive number of responders. For the children subgroup, six-, 12- and 18- month data showed 12.5%, 33.3% and 66.7% of patients, respectively, consuming at least 10 times more peanut protein than at the beginning of the trial (versus 10.5% in the placebo arm before the crossover to Viaskin® Peanut at month six, then 16.7% and 23.5%, respectively, after the crossover). Viaskin® Peanut also showed significant immunological changes (secondary efficacy endpoints) in the overall population, with clear-cut results in children. In treated children, peanut-specific IgE were increased by more than two-fold at 6-month, before decreasing and approaching toward initial levels at 18-month, while peanut-specific IgG4 (immunoglobulin G4) increased by more than eight-fold over 18-month of treatment.

Additional analyses of these data also suggest a linear relationship between body surface and response rate as well as onset of response. This analysis supports the belief that the 100 µg dose in Viaskin® Peanut used in ARACHILD was potentially too low to generate a significant clinical outcome in patients with a higher body surface. In addition, these data also suggest that levels of the antibody IGg4 are potentially a good predictor of future patient response.

*Pre-Clinical Studies*

Prior to commencing our clinical trials of Viaskin® Peanut, we completed a series of customary proof-of-concept and IND-enabling pre-clinical studies. These included *in vitro* pharmacokinetic/absorption studies, *in vivo* pharmacology studies in a mouse model of peanut allergy, and toxicology studies, as well as ISO 10993-compliant biocompatibility studies for the device component.

***Viaskin® Milk***

*Background*

CMPA is frequently the first allergy that appears during early childhood. CMPA is often missed in the primary care setting and can be a significant cause of infant distress when left undiagnosed. Symptoms can include gastrointestinal problems such as vomiting and diarrhea, skin rash, angioedema or rapid swelling of the skin, and anaphylaxis. The only option available for CMPA management is the avoidance of cow's milk, which can lead to issues of dietary imbalance, failure to thrive and poor quality of life.

In addition, cow's milk allergy is believed to be involved in many cases of EoE in children and it is estimated that EoE impacts one in every 2,000 children. EoE is a recently recognized allergic inflammatory disease, characterized by swelling of the esophagus. Typical symptoms include vomiting, abdominal pain, regurgitation, dysphagia and, in young children and infants, feeding difficulties and failure to thrive. Because the diverse and non-specific symptoms, EoE can be diagnosed only by esophageal biopsy. In addition to presenting symptoms, acute and chronic complications that may arise if EoE remains untreated include food impaction, esophageal stricture, narrow-caliber esophagus and esophageal perforation. EoE is considered to be a chronic condition with no currently approved treatments.

CMPA is the most common food allergy in infants and young children, affecting 2% to 3% of the general population. In approximately 80% of CMPA cases, the allergy to cow's milk disappears after age 16. However, according to an expert panel convened by the AAAAI, approximately 35% of children with severe CMPA subsequently develop other food allergies or allergic respiratory diseases, such as asthma.

*MILES (MILk Efficacy and Safety)*

Our product candidate for the treatment of CMPA, Viaskin® Milk, received fast track designation from the FDA in September 2016. In November 2014, we initiated our MILES trial, a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to was designed to determine a safe and effective dose in two age groups: children ages two to 11 and adolescents ages 12 to 17, and study the safety and efficacy of Viaskin® Milk in patients suffering from IgE mediated CMPA. This trial was conducted in select United States and Canadian clinical centers. In the study, 198 patients (18 patients in Part A and 180 patients in Part B) were randomized for treatment at 17 sites.

In November 2016, we announced the completion of enrollment for Part B of the MILES study, or Phase II. Part B was designed to evaluate the safety and efficacy of three doses of Viaskin® Milk (150 µg, 300 µg, 500 µg) compared to placebo for 12 months. The primary efficacy endpoint was the percentage of patients who are treatment responders after 12 months, defined as patients who meet at least one of the following criteria: (1) a 10-fold or greater increase in CRD of cow's milk proteins at month 12 of the food challenge as compared to baseline value in addition to reaching tolerance to at least 144 mg of cow's milk protein (approximately 4.5 mL of milk) or (2) a CRD of cow's milk proteins greater than or equal to 1,444 mg (approximately 45 mL of milk) at month 12 of the food challenge. Secondary efficacy endpoints included, among others, the percentage of patients who are treatment responders at month 24, the mean and median CRD of cow's milk proteins at months 12 and 24 as well as the change in CRD from baseline.

*Results of MILES*

In June 2015, we announced results for Part A of MILES, which is equivalent to Phase I, which evaluated the safety of repeated daily applications of three escalating dose-levels of Viaskin® Milk (150 µg, 300 µg and 500 µg cow's milk protein) versus placebo during three weeks in 18 patients. The DSMB for the study recommended that the study continue and expressed no safety concerns after evaluating the Part A safety data of patients treated with the three doses of Viaskin® Milk.

In February 2018, we announced preliminary results from Part B, or Phase II, of a Phase I/II study evaluating the efficacy and safety of three dose regimens of Viaskin® Milk (150 µg, 300 µg, 500 µg) in 198 patients for the treatment of IgE-mediated cow's milk protein allergy, or CMPA. This was followed by a full study presentation at the 2018 EAACI Annual Meeting in Munich, Germany, during an oral presentation by Dr. Bob Wood titled, "A Double-Blind, Placebo-Controlled Phase I/II Dose-Finding Study of Viaskin® Milk in Children and Adolescents for the Treatment of IgE-Mediated Cow's Milk Protein Allergy (CMPA): Results From MILES." Following analyses of the data, the 300 µg dose was identified as the dose with the greatest observed clinical activity for children (ITT, p=0.042). We believe these preliminary results support further advancement of the Viaskin® Milk program, and intend to discuss findings with regulatory authorities to determine the design of future studies.

The overall patient population treated according to the protocol (per-protocol analysis population) was also scientifically relevant for this dose-finding study, and the response rate that we observed with the 300 µg dose was significantly greater than placebo (p=0.027), which was consistent with ITT statistical trends. Analysis of the data showed a statistically significant response in the 300 µg arm in the two to 11 age group (ITT, p=0.042), which was identified as the prioritized population for future studies. A significant increase in CRD versus baseline as measured by changes in the month 12 DBPCFC was observed in children treated with the 300 µg dose as compared to placebo (ITT, p=0.045). The response rate and CRD for the ITT population is summarized in the table below:

**Summary of Response Rate and Cumulative Reactive Dose (CRD), ITT**

| | Placebo | Viaskin® Milk 150 µg | Viaskin® Milk 300 µg | Viaskin® Milk 500 µg |
|---|---|---|---|---|
| **Overall** | **n=53** | **n=49** | **n=49** | **n=47** |
| Responder Rate | 30.2% | 36.7% | 49.0% | 36.2% |
| Mean Change in CRD | 555.5 | 745.1 | 1,201.0* | 723.0 |
| **Children** | **n=40** | **n=38** | **n=38** | **n=36** |
| Responder Rate | 32.5% | 34.2% | 57.9%** | 38.9% |
| Mean Change in CRD | 565.6 | 624.6 | 1,322.4* | 839.8 |
| **Adolescents** | **n=13** | **n=11** | **n=11** | **n=11** |
| Responder Rate | 23.1% | 45.5% | 18.2% | 27.3% |
| Mean Change in CRD | 525.4 | 1,150.3 | 715.6 | 364.0 |

* Geometric Mean P-values for CRD, Overall: 0.008, Children: 0.045, **p=0.042

Viaskin® Milk was reported to be well-tolerated across all doses with no treatment-related SAEs. The most commonly reported adverse events were mild and moderate application site reactions. Overall, the discontinuation rate was 4.5%, with a 1.5% dropout rate due to adverse events. Treatment adherence, as measured by mean patient compliance, was over 95% in all study groups.

Overall, 98.9% of patients completing month 12 of MILES opted to enroll in the open-label portion of the study.

*Pilot Clinical Trial*

Dr. Christophe Dupont and the AP-HP conducted a double-blind, placebo-controlled pilot clinical trial of EPIT® in 2005 in children (age three months to 15 years) with high levels of specific IgE related to cow's milk protein who were unable to consume more than 10 mL of cow's milk. A publication discussing this trial's results was published in JACI in 2010. In the trial, at the end of a three-month treatment, the mean cumulative tolerated dose increment was 12-fold in the active group versus 8% in the placebo group.

At the start of the clinical trial, out of the 19 patients included, some patients could not tolerate the equivalent of one drop of milk without having severe reactions. However, after three or six months of treatment, almost half of the Viaskin® Milk treatment group was able to ingest milk in large quantities. In contrast, no patients treated during the first three months with a placebo (patch without active substance) showed meaningful improvement. These same non-responder patients were then treated with Viaskin® Milk and after three or six months of treatment, 80% of them experienced an improvement in their tolerance of milk. There were no serious or unexpected adverse events in the trial nor premature withdrawal from the clinical trial. Although larger studies are needed to confirm the statistical efficacy, we believe the results of the pilot clinical trial provide proof-of-concept for specific immunotherapy via the epicutaneous route for this indication.

*Pre-Clinical Studies*

Prior to commencing our clinical trial of Viaskin® Milk, we completed a series of customary proof-of-concept and IND-enabling pre-clinical studies. These included *in vitro* pharmacology studies in a murine model of allergies, general safety studies in a milk-sensitized animal model, genetic and other toxicology studies with the milk protein extract, and local tolerance studies, as well as biocompatibility studies of the device component.

***Viaskin® Egg***

*Background*

Hen's egg allergy is one of the most common food allergies in children. A 2011 study conducted in Australia estimated that up to 8.9% of infants react to raw egg. Several global studies suggest that egg allergy affects 1.5% to 3% of young children globally. However, most children seem to outgrow egg allergy before adolescence. A recent publication estimated that approximately 50% of children with egg allergy will become tolerant by six years of age, although resolution was highly correlated to lower egg-specific IgE levels and the absence of systemic reactions beyond topical sensitivity.

Egg-allergic reactions are mostly cutaneous in nature, including skin rashes and hives, and typically occur within 30 minutes of egg contact or ingestion. Gastrointestinal problems, such as vomiting, and respiratory complications, such as nasal congestion, are also common, but anaphylaxis is not often reported. Food allergy experts believe that about one-third of eczema patients react to food triggers, which can sometimes cause the eczema to worsen. The most common food allergen associated with eczema is egg.

*Development Program for Viaskin® Egg*

We are developing Viaskin® Egg as a treatment that we believe can reduce the clinical manifestations of hen's egg allergy. Studies also suggest that the treatment of egg allergy in young children may have a significant impact on preventing the occurrence and development of eczema.

We began pre-clinical work for this product candidate in the first half of 2015 and plan to initiate a clinical program if these studies are successful. Preclinical development is currently ongoing.

**Other Potential Viaskin® Technology Applications**

We believe that our broadly applicable technology platform, know-how and deep understanding of EPIT® positions us well to develop product candidates in areas of unmet medical need in immunotherapy. We currently expect to selectively conduct product development programs outside of our core expertise in food allergies, and will often seek to collaborate with companies or agencies that are experts in a particular field of interest. To date, we have signed several collaboration agreements to broaden the number of indications we are pursuing with our Viaskin® technology platform, while also developing other potential product candidates independently. We do not expect to provide regular updates unless and until we elect to move forward with any of these product candidates in a meaningful way:

- We are exploring the use of our technology platform in the development of diagnostic tools for food allergies. In May 2016, we announced our entry into an exclusive collaboration with Nestlé Health Science to develop MAG1C, a ready-to-use and standardized atopy patch test for the diagnosis of CMPA in infants and toddlers. Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, inclusive of an upfront payment of €10.0 million.
- With CHOP, we explored the use of our technology platform in EoE. The SMILEE (Study of Efficacy and Safety of the Viaskin® MILk in Milk-Induced Eosinophilic Esophagitis) trial which studied Viaskin® Milk in the treatment of milk-induced EoE in children ages four to 17. The trial was conducted by Dr. Jonathan Spergel at CHOP pursuant to an investigator-sponsored IND application that was accepted by the FDA in July 2015. Although we provided assistance in the form of funding and trial supplies, this trial is being conducted by CHOP and supervised by Dr. Spergel. Dr. Spergel presented the results of this trial in December 2018 and February 2019.

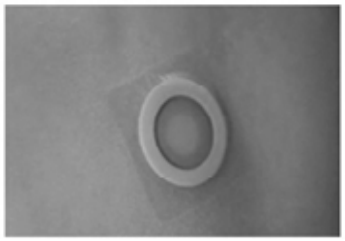
- With HUG and BioNet, we are developing Viaskin® rPT, BioNet's genetically-detoxified recombinant pertussis toxin administered by our Viaskin® patches as a booster vaccine against pertussis. In September 2016, we initiated a proof-of-concept Phase I dose-escalation, randomized, double-blind, placebo-controlled safety and immunogenicity study of Viaskin® rPT in 60 young healthy adults 18 to 40 years of age who have been vaccinated during childhood against pertussis. The primary endpoint of the trial was the incidence of treatment-emergent adverse events related to the application of Viaskin® rPT, and the secondary objectives assessed humoral responses compared to placebo. In March 2017, we announced results from the trial assessing Viaskin® rPT's ability to boost immunity against pertussis by epicutaneously administering two doses of BioNet's recombinant pertussis toxin. After further analysis of the data, limitations in study design and protocol were observed. In September 2018, we presented data from two additional cohorts at the 5th European Congress of Immunology in Amsterdam, Netherlands, which demonstrated that, following skin preparation with an epidermal laser, anti-PT booster responses elicited by Viaskin®-PT were comparable to those elicited by Boostrix® dTpa, an injectable approved booster vaccine.
- With the Icahn School of Medicine at Mount Sinai, we are investigating the efficacy and mechanism of epicutaneous tolerance utilizing our Viaskin® technology for the treatment of Crohn's disease. In December 2015, preclinical data supporting Viaskin®'s application in Crohn's was presented at Crohn's & Colitis Foundation of America Advances in Inflammatory Bowel Diseases, or AIBD, in Orlando, Florida. In May 2017, we presented preclinical data in inflammatory gastrointestinal diseases at Digestive Disease Week.
- With the Institut National de la Santé Et de la Recherche Médicale, we are developing a novel therapeutic strategy for hemophilia A with inhibitors. Data from this preclinical trial was presented during an oral presentation at the 2016 AAAAI meeting in Los Angeles, California.

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

**Manufacturing and Supply**

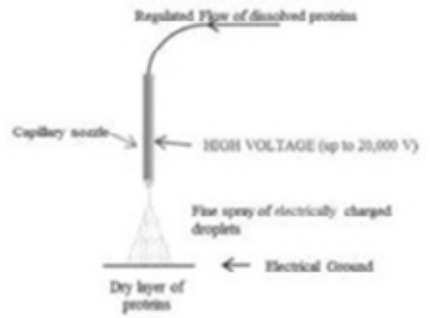
***Our Proprietary Viaskin® Technology***

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



This process sprays a liquid solution of electrically charged proteins onto the patch's backing, which is then turned into a dry solid charged particle, which remains stuck onto the patch's backing. It deposits very small and precise quantities of the active substance, devoid of adjuvants. The patch can then be stored at room temperature. We believe this patented technology is highly scalable and complies with cGMP requirements.

The principles of the Viaskin® electrospray technology are the following:




Constant liquid flows from a capillary and is subjected to a high voltage electric field (20,000 volts).

With our electrospray machine, we can transform these electrically charged liquid droplets into dry solid charged particles, and then drive them along the electric field lines onto the patch's backing.

When the electric field lines are directed toward the grounded Viaskin® patch, they force the dry particles to go directly to and only onto the patch.

We have engineered the Viaskin® patch with an electrically conductive backing in order to use an electrospray in its assembly. This conductive backing is placed under the machine's nozzles at a specified distance; the patch is also grounded so that the electric field lines can be directed onto its surface. The dry particles from the electrospray follow these field lines and settle on the patch's backing due to the attraction and conductivity produced by the electrostatic forces on the ground. Due to this process, the dry protein layers on the patch are homogenous and no loss of substance occurs during the spray. The electrostatic attraction between the particles and the medium keeps these particles attached on the patch.

With Viaskin® manufacturing technology, we believe we can achieve:

- a homogeneous layer of protein on the Viaskin® patch;
- a specific mass of active substance per Viaskin® patch;
- an adjustable active substance dosage and size for clinical trials;
- instant drying of the active substance;
- a high solubility of the active substance; and
- the possibility of spraying on the Viaskin patch both biological and chemical substances.

***Viaskin® is a Highly Scalable Manufacturing Technology***

Over the past seven years, we have tailored our electrospray technology to conduct further clinical development of our Viaskin® technology and for its subsequent commercialization.

We currently rely on a contract manufacturer, Sanofi, to manufacture the active pharmaceutical ingredients used in our Viaskin® product candidates, such as peanut protein extract. Our manufacturing machine then uses an electrospray technology to deposit the active pharmaceutical ingredient onto the Viaskin® patch. For our clinical testing, we used two different prototypes. We then developed a third-generation machine in 2009 to manufacture patches for our clinical trials. For the Phase I and II of Viaskin® Peanut clinical trials, our electrospray machine, ES GEN3.1, was able to produce 15,000 patches per batch, which was sufficient for our clinical needs.

We developed a new version of this tool, ES GEN3.2, in 2014. This new generation manufacturing tool allows us to currently produce larger batch sizes of around 80,000 patches of Viaskin® Peanut, which are compatible with our later-stage clinical development needs. Overall, on a yearly basis, ES GEN3.2's throughput can reach up to 3.5 million patches.

We completed development of a commercial-scale version of our electrospray manufacturing tool, ES GEN4.0, in the first half of 2017. This tool will allow us to produce commercial batch sizes of around 650,000 patches, compatible with initial expected market demand. Overall, on a yearly basis, ES GEN4.0's throughput is expected to reach approximately 30 million patches.

ES GEN3.1 (2009)
10 or 18 nozzles
Used for Phase I and Phase II trials
Batch size: 15,000 patches (Viaskin® Peanut 250 µg)

ES GEN3.2 (2014)
54 nozzles
Used for Phase III trials
Batch size: 80,000 patches (Viaskin® Peanut 250 µg)
Improved electrospray process, forerunner of ES GEN4.0

ES GEN4.0 (2017)
288 nozzles
To be used for commercial products
Batch size: approximately 400,000 patches
(Viaskin® Peanut 250 µg)
Scaled up to produce more patches annually

We believe our proprietary Viaskin® manufacturing technology creates high barriers to entry to our line of business, particularly in the engineering and manufacturing of our Viaskin® product candidates. We design, develop and build our manufacturing tools, and contract third-party manufacturers to operate it. We have entered into an agreement with a contract manufacturer, FAREVA, to manufacture the clinical batches of Viaskin® Peanut patches and we intend to pursue an expansion of this collaboration to manufacture commercial batches.

**Intellectual Property**

Our patent portfolio includes pending patent applications and issued patents in the United States and in foreign countries. These patents and applications generally fall into four broad categories:

- patents and patent applications we co-own with AP-HP and the Université de Paris-Descartes relating to the Viaskin® electrostatic patch and its use, half of which may expire as early as 2022;
- patents and patent applications which we own relating to our electrospray method of manufacturing the Viaskin® electrostatic patch, which may expire as early as 2029;
- patents and patent applications we co-own with AP-HP and the Université de Paris-Descartes relating to the treatment of peanut allergies using our Viaskin® patch technology, which may expire as early as 2028; and
- a variety of other patent applications that we own or co-own relating, for example, to prophylactic uses of the Viaskin® patch technology and to treatment of other indications using the Viaskin® patch technology.

The term of a U.S. patent may be eligible for patent term extension under the Hatch-Waxman Act to account for at least some of the time the drug or device is under development and regulatory review. With regard to a drug or device for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or 14 years from the date of the FDA approval of the drug or device. Some foreign jurisdictions have analogous patent term extension provisions that allow for extension of the term of a patent that covers a device approved by the applicable foreign regulatory agency. In the future, if and when our Viaskin® electrostatic patch receives FDA approval, we expect to apply for a patent term extension on the patent that we believe will provide the best exclusivity position if extended.

**Co-Ownership Agreement**

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

In December 2008, we entered into an assignment, development and co-ownership agreement with AP-HP and Université Paris-Descartes, or UPD, by which we agreed to terms of co-ownership with AP-HP and UPD of certain U.S. and foreign patents and patent applications, referred to herein as the shared patents. We, and any licensees or sublicensees that we designate, have the exclusive right to commercial uses of the shared patents. AP-HP and UPD agreed to use the shared patents only for internal research purposes and not to license the shared patents to any third party. Upon commercialization of any product covered by the shared patents, which we expect would include our Viaskin® product candidates, we will be obligated to pay AP-HP and UPD a percentage of net sales as a royalty. This royalty is in the low single digits and varies depending on the particular patent used in the product. Additionally, if we license any of the shared patents to a third party and a licensee commercializes products covered by such shared patents, we will be obligated to pay AP-HP and UPD a percentage in the low single digits of the money that we receive from our licensee.

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

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

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

**Competition**

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Significant competitive factors in our industry include product efficacy and safety: quality and breadth of an organization's technology; skill of an organization's employees and its ability to recruit and retain key employees; timing and scope of regulatory approvals; government reimbursement rates for, and the average selling price of, products; the availability of raw materials and qualified manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities.

We cannot assure you that any of our products that we successfully develop will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

Our competitors may also succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we are able to do, which could place us at a significant competitive disadvantage or deny us marketing exclusivity rights. Market acceptance of our product candidates will depend on a number of factors, including: (1) potential advantages over existing or alternative therapies or tests; (2) the actual or perceived safety of similar classes of products; (3) the effectiveness of sales, marketing, and distribution capabilities; and (4) the scope of any approval provided by the FDA or foreign regulatory authorities.

Although we believe our product candidates possess attractive attributes, we cannot assure you that our product candidates will achieve regulatory or market acceptance, or that we will be able to compete effectively in the biopharmaceutical drug markets. If our product candidates fail to gain regulatory approvals and acceptance in their intended markets, we may not generate meaningful revenues or achieve profitability.

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

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

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

To our knowledge, other pharmaceutical and biotechnology companies are also seeking to develop food allergy treatments, although many are in the discovery or preclinical stages. For example, Aimmune Therapeutics, Inc., or Aimmune, reported topline results from its Phase III trial evaluating the safety and efficacy of its OIT product candidate, AR101, in peanut allergic patients in February 2018. In March 2019, Aimmune announced that its BLA for AR101 was accepted for review by the FDA. To our knowledge, the company uses a formulation of peanut flour for oral administration intended for oral desensitization to peanut. We are also aware of other companies developing OIT product candidates, as well as other companies that are working on recombinant peanut proteins capable of initiating an attenuated immune response of using subcutaneous administration. We are also aware that Sanofi S.A., or Sanofi, has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp., (acquired by Merck) and may pose a competitive risk to our products in the future. Aimmune also announced a clinical collaboration with Regeneron Pharmaceuticals, Inc. and Sanofi to study AR101 treatment with dupilumab in peanut allergic patients, and commenced a Phase II clinical trial in October 2018 under this collaboration. We believe Regeneron and Sanofi are also planning to study dupilumab as a monotherapy in the treatment of peanut allergic patients. In August 2018, Genentech, Inc. and Novartis Pharmaceuticals Corporation announced that the FDA granted breakthrough designation for Xolair for the prevention of severe allergic reactions following accidental exposure to one or more foods in people with allergies. The companies plan to initiate a potentially pivotal trial in multiple food allergies. In March 2018, AnaptysBio, Inc. announced top-line proof-of-concept data for its ongoing Phase IIa trial to evaluate the safety of its IL-33 inhibitor product candidate, ANB020, in severe adult peanut allergic patients. In August 2018, AnaptysBio announced that it will deprioritize the development of ANB020 in peanut allergy.

**Government Regulation**

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

***U.S. Biological Product Development***

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA’s refusal to approve pending

applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

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

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

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion.

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

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

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse, findings from other studies suggesting a significant risk to humans exposed to the drug, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

*BLA and FDA Review Process*

Following trial completion, trial data is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety,

purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing. The application includes both negative or ambiguous results of pre-clinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

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

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

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

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

There is no assurance that the FDA will ultimately approve a product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and

specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase IV testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

*Review and Approval of Combination Products in the United States*

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products;
- a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, device, or biological packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect. Our Viaskin® product candidates are combination products comprising a device for delivery of a biologic. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product, which means the mode of action expected to make the greatest contribution to the overall intended therapeutic effects. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biologic product, that is, if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, the FDA center responsible for premarket review of the biologic product would have primary jurisdiction for the combination product.

*Expedited Development and Review Programs*

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

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

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

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

The limitations imposed would be commensurate with the specific safety concerns presented by the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

*Breakthrough Designation*

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

*Pediatric Trials*

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. FDASIA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase II meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments

to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers.

*Post-Marketing Requirements*

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling, also known as off-label use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the product or its labeling or changes of the site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. Moreover, the constituent parts of a combination product retain their regulatory status, for example, as a biologic or device, and as such, we may be subject to additional requirements in the Quality System Regulation, or QSR, applicable to medical devices, such as design controls, purchasing controls, and corrective and preventive action. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase IV testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

*Other Regulatory Matters*

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs, among other activities, must also comply with state and federal fraud and abuse laws, data privacy and security laws, transparency laws, and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, the exclusion from participation in federal and state healthcare programs or refusal to allow a firm to enter into supply contracts, including government contracts, integrity obligations and individual imprisonment. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

*U.S. Patent Term Restoration and Marketing Exclusivity*

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

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009, or BPCIA. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a biological

product be biosimilar to the reference product and the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product. A reference biological product is granted twelve years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

***European Union Drug Development***

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

Similar to the United States, the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the European Union clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the European Union Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the Member State regimes. To improve the current system, a new Regulation No. 536/2014 on clinical trials on medicinal product candidates for human use, which repealed Directive 2001/20/EC, was adopted on April 16, 2014 and published in the European Official Journal on May 27, 2014. The new Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency. The new Regulation entered into force on June 16, 2014 but will not be applied before 2020 (its enactment will occur six months after the publication of a notice delivered by the European Commission on the European Union clinical trial portal and database, expected for 2019 according to the European Commission's website). Until then the Clinical Trials Directive 2001/20/EC will still apply. In addition, the transitory provisions of the new Regulation offer the sponsors the possibility to choose between the requirements of the Directive and the Regulation for one year from the entry into application of the Regulation.

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

*European Union Drug Review and Approval*

In the European Economic Area, or EEA (which is comprised of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA on the date on which Regulation No. 726/2004 enters into force or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Concerned Member States, or CMSs) for their approval. If the CMSs raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the CMSs).

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

**Other Regulatory Matters**

*French Regulatory Framework*

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

In France, for example, Directive No. 2001/20/EC has been transposed by Act No. 2004-806 of August 9, 2004 relative to the public health policy and Decree No. 2006-477, April 26, 2006, modifying the title of the Code of Public Health dedicated to biomedical research. This regulation replaces the notification procedure arising from the Huriet-Sérusclat Act of December 20, 1988. The Act of August 9, 2004 was notably amended by the Act of March 5, 2012 and by the ordinance of June 16, 2016, which mostly aims at (i) adapting the provisions relating to clinical research to the new European Regulation No. 536/2014, (ii) a better response coordination among Ethical Research Committees in charge of reviewing research agreements and (iii) harmonizing data protection provisions with the latest legislative developments (Jardé Act). The Jardé Act was inapplicable for a long time, and applicable since November 18, 2016, date of its enforcement decree.

Article L. 1121-4 of the Public Health Code, as amended by the Ordinance of June 16, 2016, establishes a system of prior authorization issued by the ANSM and/or of a favorable opinion of a competent Ethical Research Committee, depending on the type of clinical trial. Since the entry into force of the Jardé Act, the competent Ethical Research Committee is selected randomly by drawing lots (article L.1123-6 of the Public Health Code). On the basis of Article L. 1123-7 of the same code, the Ethical Research Committee shall deliver its opinion on the research's conditions of validity, particularly with respect to participant protection, their information and how they collect informed consent, as well as the project's general relevance, the satisfactory nature of the assessment of benefits and risks and the adequacy between the objectives pursued and the means implemented. The ANSM, after submission of the complete file containing not only information on the clinical protocol, but also specific product data and its quality control, as well as results of pre-clinical studies may inform the sponsor that it objects to the implementation of the research. The sponsor can then modify the contents of his research project and submit this amended or supplemented request to the ANSM. If the sponsor does not alter the content of its request, the request is considered rejected.

Under the terms of the Decree of April 26, 2006, the time limit for the examination of a request for authorization cannot exceed 60 days from the receipt of the complete file (R.1123-32 of the Public Health Code). Finally, under Article L. 1123-11, in the event of risk to public health or if the ANSM considers that the conditions in which the research is implemented no longer correspond to the conditions indicated in the request for authorization or does not comply with the provisions of the Public Health Code, it may at any time request changes to procedures for the realization of research, and suspend or ban this research. The decision of November 24, 2006 sets the rules for Good Clinical Practice for biomedical research on medicines for human use provided for in Article L. 1121-3 of the Public Health Code. The purpose of Good Clinical Practice, or GCP, is to ensure both the reliability of data arising from clinical trials and the protection of persons participating in these clinical trials. GCPs shall apply to all clinical trials, including pharmacokinetics, bioavailability and bioequivalence studies in healthy volunteers and Phase II to IV clinical trials.

Personal data collected during clinical trials must be reported to the French data protection authority, and kept in the record of processing activities held by the data processor pursuant to the Regulation 2016/679 of April 27, 2016, French Act No. 78-17 of January 6, 1978, , concerning computing, files and freedoms. According to the aforementioned regulations, patients have, among others, a right to their data and a right of rectification of such data, as the case may be.

*French Pharmaceutical Company Status*

To date, we have been granted by the ANSM the status of pharmaceutical establishment ("*établissement pharmaceutique*") solely for the purpose of conducting quality control activities on the Bagneux site, and therefore, cannot either manufacture the product candidates we develop or directly consider their marketing. Obtaining the pharmaceutical establishment license, either as distributor "exploitant" or as manufacturer, requires the submission of a request file specific to each of the two qualifications with the ANSM, which only grants it after review of this file and evaluation, usually after verification that the company has adequate premises, the necessary personnel and an adapted structure with satisfactory procedures for carrying out the proposed pharmaceutical activities.

We currently entrust CMOs with the manufacturing of clinical batches and intend to continue relying on CMOs for the production of the first commercial batches. We may consider internalizing production once our first product candidate is approved by the regulatory authorities.

***Reimbursement***

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

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

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

For example, the ACA, enacted in March 2010, has significantly impacted the health care industry. The ACA was expansive health reform legislation designed to expand coverage for the uninsured while at the same time containing overall healthcare costs enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, and other changes. With regard to biopharmaceutical products, among other things, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare Part D program. However, some provisions of the ACA have yet to be fully implemented and certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump Administration to repeal or replace certain aspects of the ACA.

For example, since January 2017, President Trump signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Additionally, on December 22, 2017, President Trump signed into law The Tax Cuts and Jobs Act of 2017, or Tax Act, which included a provision repealing the individual mandate to maintain health insurance coverage under the ACA effective January 1, 2019. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain mandated fees under the ACA, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans and the annual fee imposed on certain health insurance providers based on market share. In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While neither the Texas District Court Judge, Trump administration nor CMS have stated that the ruling will have an immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts will impact the ACA.We continue to evaluate how the ACA and recent efforts to limit the implementation of the ACA will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction was tasked with recommending to Congress proposals in spending reductions. Because they did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, it triggered the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Additionally, in the United States, there have been several recent Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation. The Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The United States Department of Health and Human Services has already started the process of soliciting feedback on some of these measures while concurrently implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Additional legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market any products and generate revenues. Cost containment measures that healthcare payors and providers are instituting and the effect of further healthcare reform could significantly reduce potential revenues from the sale of any of our product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective access to the market assumes that our future products will be supported by the hospital (through an agreement for local communities) or reimbursed by social security. The price of medications is negotiated with the Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Indeed, the price of medicinal products is negotiated between each pharmaceutical company and the CEPS as part of a master agreement between the French pharmaceutical companies association, or the LEEM, and the CEPS. The latest master agreement was signed on December 31, 2015 and will remain applicable until December 31, 2019.

***Other Healthcare Laws and Compliance Requirements***

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

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

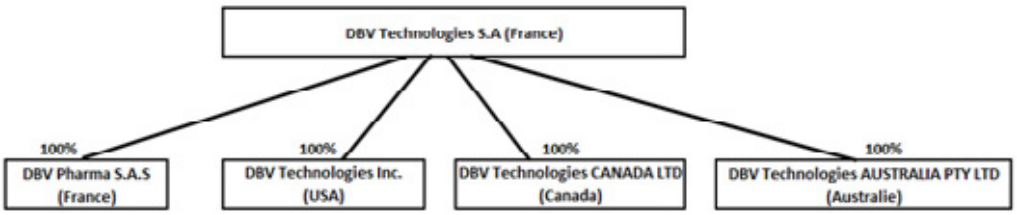
individual for, or the purchase, lease, order, or recommendation of, an item, good, facility or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities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

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which impose penalties and provide for civil whistleblower or qui tam actions against individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, including for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, knowingly and willfully falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters, knowingly and willfully embezzling or stealing from a healthcare benefit program, or willfully obstructing a criminal investigation of a healthcare offense. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations;
- HIPAA, as amended by the HITECH Act, and its implementing regulations, which imposes certain requirements on covered entities and their business associates relating to the privacy, security and transmission of individually identifiable health information; and
- state, local and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant administrative, civil, and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to administrative, civil, and/or criminal sanctions, including individual imprisonment and exclusion from government funded healthcare programs.

**C. Organizational Structure**

The following diagram illustrates our corporate structure:




**D. Property, Plants and Equipment.**

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,770 square meter facility consisting of office and laboratory space, pursuant to a lease agreement dated March 3, 2015, which expires on March 8, 2024. We also have two facilities in Bagneux, France. These facilities consist of 2,237 square meters of office and laboratory space and are used primarily by our industrial and production teams. In April 2018, we entered into an addendum to our lease for an additional 500 square meters of office space in building B of Green Square, Bagneux, France. These facilities are leased under one agreement, which expires on May 31, 2020. We entered into an additional lease for offices in Montrouge, France in July 2018. This facility consists of 1,808 square meters of office space, pursuant to a lease agreement dated July 1, 2018, which expires on June 30, 2027.

We also have an office in North America to support our U.S. subsidiary as well as future commercialization needs. We lease 3,780 square feet of office space in Tower 49, New York, New York. This lease is for a period of 65 months and expires on February 25, 2023.

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

**Item 4. A. Unresolved Staff Comments.**

Not applicable.

**Item 5. Operating and Financial Review and Prospects.**

**Overview**

We are a clinical-stage specialty biopharmaceutical company focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin®. Our therapeutic approach is based on epicutaneous immunotherapy, or EPIT®, our proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaski®n. We have generated significant data demonstrating that Viaskin®'s mechanism of action is novel and differentiated, as it targets specific antigen-presenting immune cells in the skin, called Langerhans cells, that capture the antigen and migrate to the lymph node in order to activate the immune system without passage of the antigen into the bloodstream, minimizing systemic exposure in the body. We are advancing this unique technology to treat patients, including infants and children, suffering from food allergies, for whom safety is paramount, since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such an anaphylactic shock.

We initially financed our operations through several private equity investments totaling €38.7 million. In 2012, we completed a €40.6 million initial public offering of our ordinary shares on Euronext Paris. In 2013, we completed a €29.9 million private investment in public equity, or PIPE, of which we received net proceeds of €15.1 million and our selling shareholders received net proceeds of €14.8 million. In 2014, we completed a €104.5 million global underwritten public offering of both ADSs on the Nasdaq Global Select Market, or Nasdaq, and ordinary shares on Euronext Paris, issuing an aggregate of 3,074,686 ordinary shares, from which we received net proceeds of €93.7 million. In July 2015, we completed a €255.3 million underwritten public offering of 4,140,000 ordinary shares in the form of 8,280,000 ADSs, from which we received net proceeds of €237.3 million. In connection with our 2015 public offering, our share capital increased by €414 thousand with a corresponding increase of €236.9 million in our share premium. In March 2018, we completed an underwritten global offering of an aggregate of 4,056,914 ordinary shares in (i) a public offering of 1,600,817 ordinary shares in the form of 3,201,634 ADSs in the United States, Canada and certain other countries outside Europe and (ii) a concurrent private placement of 2,456,097 ordinary shares in Europe (including France), from which we received gross proceeds of €140.8 million. In connection with our 2018 public offering, our share capital increased by €0.4 million with a corresponding increase of €140.4 million in our share premium, gross.

We have incurred net losses in each year since our inception. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations.

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

- continue the development of our product candidates, including planned and future clinical trials;
- seek regulatory approvals for our product candidates;
- prepare for the potential launch and commercialization of our product candidates, if approved;
- establish a sales and marketing infrastructure for the commercialization of our product candidates, if approved; and
- 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.

We do not expect to generate material revenue from product sales unless and until we successfully complete development of, and obtain marketing approval for, one or more of our product candidates, which we expect may take a number of years and is subject to significant uncertainty. Until we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding and collaborations such as the collaboration we entered into with Nestlé Health Science, strategic alliances and licensing arrangements or a combination of these approaches. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our development programs or commercialization efforts or grant to others rights to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to cease operations, in part or in full. More specifically, as we continue to prepare for the potential launch of our Viaskin® Peanut product candidate in North America planned in 2020, for which its BLA submission to the US FDA is expected in the third quarter of 2019. We expect operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support our operating plan for the next 12 months despite additional funds raised in March 2018. We expect to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding our ability to continue as a going concern. We expect to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

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

Our financial statements for 2016, 2017 and 2018 have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

**Financial Operations Overview**

***Operating Income***

Our operating income consists of other income as we generated no revenue in 2016, 2017 or 2018.

***Other Income***

*Government Assistance*

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

*Research Tax Credits*

The research tax credit (*crédit d'impôt recherche*), or CIR, is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies demonstrating that they have expenditures that meet the required criteria, including research expenditures located in France or, since January 1, 2005, within the European Community or in another state that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause, receive a tax credit which can be used against the payment of the corporate tax due on the fiscal year in which the expenditures were made and during the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the CIR only involve research expenses.

The main characteristics of the CIR are the following:

- the CIR results in a cash inflow to us from the tax authorities, i.e., it is used to offset the payment of corporate tax or is paid directly to us for the portion that remains unused;
- a company's corporate income tax liability does not limit the amount of the CIR — a company that does not pay any corporate income tax can request direct cash payment of the research tax credit; and
- the CIR is not included in the determination of the corporate income tax.

As a result, we have concluded that the CIR meets the definition of a government grant as defined in IAS 20 "*Accounting for Government Grants and Disclosure of Government Assistance*" and that the classification as other income within operating income in our statement of income (loss) is appropriate.

We received the reimbursement of the CIR for the 2017 fiscal year in 2018. We will request the reimbursement of the 2018 fiscal year CIR under the applicable rules and expect to be reimbursed in 2019.

*Collaboration agreement with Nestlé Health Science*

In May 2016, we announced our entry into an exclusive global collaboration with Nestlé Health Science for the development and, if approved, commercialization of MAG1C, an innovative, ready-to-use and standardized atopy patch test for the diagnosis of CMPA in infants and toddlers.

Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C up through a Phase II clinical trial and a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Science will support the commercialization of MAG1C globally, while prioritizing certain agreed-upon countries. We are eligible to receive up to €100.0 million in potential development, clinical, regulatory and commercial milestones, including an upfront payment of €10.0 million. As of December 31, 2018, we had recorded deferred revenue of €6.5 million related to our collaboration with Nestlé Health Science, which will be deferred and recognized ratably over the service obligation period. We expect the service obligation period to be completed in the second half of 2021.

***Operating Expenses***

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

**Research and Development**

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

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

Our research and development expenses in the periods presented mainly relate to the following activities:

- Viaskin ®Peanut for the treatment of peanut allergy in children, adolescents and adults. In the fourth quarter of 2017, we completed a Phase III global program designed to assess the efficacy and safety of Viaskin® Peanut in children four to 11 years of age including the Peanut EPIT® Efficacy and Safety Study, or PEPITES, in 356 peanut allergic patients four to 11 years of age, as well as the REAL Life Use and Safety of EPIT®, or the REALISE study, which was designed to assess the use and safety of Viaskin® Peanut 250 µg in routine clinical practice in 393 peanut allergic patients four to 11 years of age. The PEOPLE trial, the open-label extension trial of PEPITES, completed enrollment in August 2017. We completed the Viaskin® Peanut's Efficacy and Safety, or VIPES, study, a Phase IIb clinical trial of Viaskin® Peanut, in the third quarter of 2014, which was followed by OLFUS-VIPES, an open-label extension trial of VIPES. The topline results from the two-year OLFUS-VIPES were announced in October 2016. In August 2017, we initiated the EPIT® in Toddlers with Peanut Allergy, or EPITOPE, a Phase III clinical trial assessing the safety and efficacy of Viaskin® Peanut for the treatment of peanut allergic patients one to three years of age. In September 2018, we announced that the independent data and safety monitoring board, or DSMB, completed its planned safety review of Part A of the EPITOPE trial of Viaskin® Peanut in peanut allergic toddlers ages one to three. The DSMB did not identify any safety concerns for patients enrolled in Part A of the trial and recommended that the trial continue as planned with the 250 µg dose selected for investigation in Part B. In October 2018, following a positive DSMB meeting, we announced the initiation of Part B of the EPITOPE trial, which will evaluate peanut allergic patients for 12 months. We expect to enroll approximately 400 toddlers for Part B in the United States, Europe, Australia and Canada.
- Viaskin® Milk for the treatment of Immunoglobulin E, or IgE, mediated CMPA in children. The Milk Efficacy and Safety, or MILES, study, a Phase I/II study designed to determine a safe and effective dose in two age groups: children ages 2 to 11 and adolescents ages 12 to 17 with IgE-mediated cow's milk protein allergy, or CMPA completed enrollment in November 2016. Topline results were reported in February 2018. An open-label extension trial is ongoing for up to four years.

- Scaling of the Viaskin® technology. Our efforts to increase our production capacity to support the commercialization of Viaskin® Peanut, if approved, are currently ongoing.
- Select proof-of-concept clinical trials and preclinical studies using the Viaskin® platform in the field of inflammatory and autoimmune diseases are currently underway. Of note, the Study of efficacy and safety of the Viaskin® MILk in Milk-Induced Eosinophilic Esophagitis, or EoE, in Children, or SMILEE, is an investigator-initiated Phase II trial investigating the use of Viaskin® Milk for treatment of EoE in approximately 20 patients four to 17 years of age. SMILEE was conducted at the Children's Hospital of Philadelphia. A Phase I study of Viaskin® rPT in the reactivation of immunity against Bordetella pertussis in 60 healthy adults was conducted in collaboration with the Geneva University Hospitals (HUG) and BioNet-Asia Co. Ltd.

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

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

In the year ended December 31, 2018, we spent €107.2 million in research and development expenses to advance the development of our product candidates. The following table provides a breakdown of our direct research and development expenses for our two lead development programs, as well as expenses not allocated to the programs and share-based compensation expenses included in research and development expenses, for the years ended December 31, 2016, 2017 and 2018, respectively:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (thousands of Euros) | | |
| Research and development expenses related to Viaskin® Peanut[1] | €26,789 | € 43,585 | € 59,162 |
| As a percentage of research and development expenses, excluding share-based compensation expense | 45% | 49% | 62% |
| Research and development expenses related to Viaskin® Milk[1] | € 8,478 | € 8,348 | € 8,425 |
| As a percentage of research and development expenses excluding share-based compensation expense | 14% | 9% | 9% |
| Other research and development expenses[1] | €24,790 | € 36,937 | € 27,265 |
| Total research and development expenses, excluding share-based compensation expense | €60,057 | € 88,870 | € 94,852 |
| Share-based compensation expenses included in research and development expenses | €18,771 | € 16,362 | € 12,319 |
| Total research and development expenses | **€78,828** | **€105,232** | **€107,171** |

(1) Excludes employee share-based compensation expense.

We cannot determine with certainty the duration and completion costs of the current or future clinical trials of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory

approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expense of our ongoing as well as any additional non-clinical studies, clinical trials and other research and development activities;
- clinical trial and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for Viaskin® Peanut or any other product candidate that we may develop in the future.

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

**General and Administrative**

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

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

**Sales and Marketing**

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

**Finance Income (Expense)**

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

**Critical Accounting Policies and Estimates**

Our financial statements are prepared in accordance with IFRS. Some of the accounting methods and policies used in preparing our financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the facts and circumstances concerned. The actual value of our assets, liabilities and shareholders' equity and of our earnings could differ from the value derived from these estimates if conditions changed and these changes had an impact on the assumptions adopted. We believe that the most significant management judgments and assumptions in the preparation of our financial statements are described below. See Note 3 to our financial statements for a description of our other significant accounting policies.

***Revenue Recognition***

Regarding the first application of *IFRS 15* on January 1, 2018, an analysis has been completed on performance conditions, revenue recognition method for milestones payment and on the sale price allocation for the collaboration contract signed with Nestlé in 2016. It has been determined that the license and developments to be made by us are a unique performance obligation.

As a result, we have concluded that under *IFRS 15*, revenue related to the contract will be recognized progressively, up to the costs incurred by us at the end of 2018. No margin is recognized at this stage of the development. Deferred revenue is recognized and reversed over the period in which there is a contractual obligation.

As a result, the application of IFRS 15 had no impact on the financial statements as at December 31, 2018, and retrospectively as at December 31, 2017.

***Share-Based Compensation***

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

Determining the fair value of share-based awards at the grant date requires judgment. We use the Black-Scholes option-pricing model to determine the fair value of share options. The determination of the grant date fair value of options using an option-pricing model is affected by assumptions regarding a number of complex and subjective variables. These variables include the expected term of the options, our share price volatility, risk-free interest rates, and expected dividends, which are estimated as follows:

*Fair Value of Our Ordinary Shares.* We established a policy of using the closing sales price per ordinary share as quoted on Euronext Paris on the date prior to the date of grant for purposes of determining the fair value of ordinary shares with a floor value of the average of the closing sales price per ordinary share for the 20 trading days preceding the grant.

*Expected Term.* The expected term represents the period that our share-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the share option awards granted, we have based our expected term on the simplified method, which represents the average period from vesting to the expiration of the award.

*Expected Volatility.* We are using our volatility on Euronext Paris observed on historical dataset from our stock quote.

*Risk-Free Interest Rate.* The risk-free interest rate is based on the yields of French government bonds with maturities similar to the expected term of the options for each option group.

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

If any of the assumptions used in the Black-Scholes model changes significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The following table presents the weighted-average assumptions used to estimate the fair value of options granted during the periods presented:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| Volatility | 49% | 42% | 47% |
| Risk free interest rate | -0.32%-0.39% | -0.23%-0.61% | 0.14%-0.37% |
| Expected life (in years) | 5.5-7.0 | 5.5-7.0 | 5.5-7.0 |
| Dividend yield | — | — | — |

For 2016, 2017 and 2018, we recorded employee share-based compensation expense of €34.7 million, €30.8 million and €26.0 million, respectively.

**A. Operating Results**

***Comparisons for the Years Ended December 31, 2016 and 2017***

*Operating Income*

We generated operating income of €11.9 million in 2017 compared to €9.1 million in 2016, an increase of 31.1%. This income was mainly generated by our CIR and by revenue recognized under our collaboration agreement with Nestlé Health Science, and more marginally, by subsidies received for research projects conducted by us.

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2017 |
| | (Amounts in thousands of Euros) | |
| Sales | — | — |
| Other income | 9,084 | 11,909 |
| *Research tax credit* | 7,228 | 9,330 |
| *Subsidies* | 303 | 271 |
| *Other operating income* | 1,554 | 2,308 |
| **Total income** | **9,084** | **11,909** |

For the year ended December 31, 2017, we recorded other income related to CIR of €9.2 million. In 2016, we recorded other income related to CIR of €7.2 million, which we requested for reimbursement in 2017. In 2017, we received the reimbursement of €7.3 million (including a €0.1 million adjustment) for the 2016 CIR under the community small and medium business scheme.

The increase of €2.0 million, or 29.1%, in the CIR recorded in 2017 from the CIR recorded in 2016 reflects the acceleration of our various development programs in 2017, mainly due to simultaneously conducting clinical trials for both Viaskin® Peanut and Viaskin® Milk.

In 2017, we recognized revenue of €1.9 million under our collaboration with Nestlé Health Science, which was previously recorded as deferred revenue.

*Research and Development Expenditures*

From 2016 to 2017, the total amount spent by us for research and development activities increased by €26.4 million to €105.2 million, or an increase of 33.5%.

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

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2017 |
| | (thousands of Euros) | |
| Personnel expenses | 32,777 | 37,112 |
| Sub-contracting, collaborations and consultants | 34,413 | 54,397 |
| Research supplies | 1,234 | 1,464 |
| Rental | 1,903 | 2,018 |
| Conferences and travel expenses | 2,387 | 2,807 |
| Depreciation and amortization | 1,141 | 2,424 |
| Small equipment and other supplies | 2,675 | 2,646 |
| Others | 2,298 | 2,364 |
| **Total research and development expenses** | **78,828** | **105,232** |

The increased research and development expenses in 2017, compared to 2016, resulted from costs associated with the PEPITES and REALISE Phase III trials of Viaskin® Peanut, the EPITOPE Phase III trial of Viaskin® Peanut, the MILES Phase I/II trial of Viaskin® Milk, as well as a substantial increase in research and development personnel in order to support our increasing number of active development programs.

In particular, we have incurred:

- an increase of 13.2% in total payroll associated with research and development, resulting from:
  - an increase in research and development employee-related expense resulting primarily from the increase in average staff to 162 employees at the end of 2017 from 126 employees at the end of 2016. As of December 31, 2017, employee-related expense amounted to €20.8 million compared to €14.0 million as of December 31, 2016, or an increase of 48.1%;
  - a decrease in share-based compensation expense. Share-based compensation expense related to research and development employees amounted to €18.8 million and €16.2 million as of December 31, 2016 and 2017, respectively.
- an increase of 58.1% in sub-contracting, collaboration and consultant costs, which includes the costs of our service providers supporting:
  - the completed Phase III PEPITES trial for Viaskin® Peanut, for which we reported topline results in October 2017, and the completed Phase III REALISE trial, for which we reported topline results in November 2017;
  - the Phase III EPITOPE trial for Viaskin® Peanut, which was initiated in August 2017;
- the MILES trial for Viaskin® Milk, for which we reported topline results in February 2018;
- the SMILEE study, a Phase IIa investigator-initiated clinical trial for Viaskin® Milk for the treatment of milk-induced EoE in pediatric patient populations, which completed enrollment in February 2017; and
- the Phase I study of Viaskin® rPT for pertussis booster vaccination in collaboration with BioNet-Asia Co. Ltd. and HUG, for which we reported topline results in March 2017.

*General and Administrative Expenses*

General and administrative expenses were €35.8 million in 2017, compared to €35.0 million in 2016, or an increase of 2.4%.

Our general and administrative expenses are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2017 |
| | (thousands of Euros) | |
| Personnel expenses | 22,613 | 19,742 |
| Fees | 7,701 | 10,347 |
| Insurance policies | 1,853 | 1,367 |
| Corporate communication and travel expenses | 1,136 | 1,599 |
| Rental | 501 | 584 |
| Depreciation and amortization | 181 | 422 |
| Others | 1,020 | 1,776 |
| **Total general and administrative expenses** | **35,005** | **35,837** |

The increase of €0.8 million in general and administrative expenses was primarily due to:

- an increase of 34.4% in fees primarily associated with advisor and consultant fees incurred in 2017 to support the implementation of our new information system, as well as an increase in legal and corporate communications fees;
- an increase of 40.7% in expenses related to our corporate communications and investor relations efforts.

Those increases were partially offset by:

- a decrease of 12.7% in total general and administrative payroll resulting from the decrease in share-based compensation expense. Those decreases are partially offset by the salary costs related to an increase from 31 employees at the end of 2016 to 44 employees at the end of 2017. Excluding the share-based expense, the decrease of general and administrative employee-related expenses was 6.2%.
- a decrease of 26.2% in insurance policy expenses, due to the July 2016 expiration of our directors and officers liability insurance.

*Sales and Marketing Expenses*

During the period presented, our sales and marketing expenses increased from €15.8 million in 2017, compared to €11.3 million in 2016, or an increase of 40.3%. Sales and marketing expenses primarily include payroll for U.S. employees in our sales and marketing function, as well as fees related to pre-commercialization activities for Viaskin® Peanut in North America.

| | Year Ended December 31, | |
|---|---|---|
| | 2016 | 2017 |
| | (thousands of Euros) | |
| Personnel expenses | 4,954 | 6,976 |
| Fees | 4,447 | 2,480 |
| Marketing, tradeshows and travel expenses | 1,393 | 5,984 |
| Others | 487 | 384 |
| **Total sales and marketing expenses** | **11,282** | **15,824** |

Our direct sales and marketing expenses consist principally of personnel expenses and market research consultant fees.

The increase of 40.3% in total payroll associated with sales and marketing results primarily from both an increase in staff from 7 employees at the end of 2016 to 10 employees at the end of 2017, and from an increase in share-based compensation expense. Excluding share-based expense, the increase of our sales and marketing employee-related expenses was 24.7%.

*Financial Profit (Loss)*

Our net financial loss was €2.7 million in 2017, compared to a net financial profit of €1.5 million in 2016. The variation is mainly attributable to the unrealized exchange effect of U.S.-dollar-denominated intercompany advances.

***Comparisons for the Years Ended December 31, 2017 and 2018***

*Operating Income*

We generated operating income of €14.5 million in 2018 compared to €11.9 million in 2017, an increase of 22.1%. This income was mainly generated by our CIR and by revenue recognized under our collaboration agreement with Nestlé Health Science, and more marginally, by subsidies received for research projects conducted by us.

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| | (Amounts in thousands of Euros) | |
| Sales | — | — |
| Other income | 11,909 | 14,537 |
| *Research tax credit* | 9,330 | 11,034 |
| *Subsidies* | 271 | 152 |
| *Other operating income* | 2,308 | 3,351 |
| **Total income** | **11,909** | **14,537** |

For the year ended December 31, 2018, we recorded other income related to CIR of €11.0 million. In 2017, we recorded other income related to CIR of €9.3 million, which we requested for reimbursement in 2018. In 2018, we received the reimbursement of €9.5 million (including a €0.3 million adjustment) for the 2017 CIR under the community small and medium business scheme.

The increase of €1.7 million, or 18.3%, in the CIR recorded in 2018 from the CIR recorded in 2017 reflects the acceleration of our various development programs in 2018, mainly due to simultaneously conducting clinical trials for both Viaskin® Peanut and Viaskin® Milk.

In 2018, we recognized revenue of €3.0 million under our collaboration with Nestlé Health Science.

*Research and Development Expenditures*

From 2017 to 2018, the total amount spent by us for research and development activities increased by €2 million to €107.2 million, or an increase of 1.8%.

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

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| | (thousands of Euros) | |
| Personnel expenses | 37,112 | 37,912 |
| Sub-contracting, collaborations and consultants | 54,397 | 52,927 |
| Small equipments and other supplies | 4,110 | 4,771 |
| Rental | 2,018 | 2,703 |
| Conferences and travel expenses | 2,807 | 2,591 |
| Depreciation and amortization | 2,424 | 2,492 |
| Others | 2,364 | 3,776 |
| **Total research and development expenses** | **105,232** | **107,171** |

The increased research and development expenses in 2018, compared to 2017, resulted from costs associated with the PEPITES and REALISE Phase III trials of Viaskin® Peanut, the EPITOPE Phase III trial of Viaskin® Peanut, the MILES Phase I/II trial of Viaskin® Milk, as well as a substantial increase in research and development personnel expenses in order to support our increasing number of active development programs.

In particular, we have incurred:

- An increase of 2.2% in total payroll associated with research and development, resulting from an increase in average research and development staff from 176 employees at the end of December 2017 to 191 employees at the end of December 2018 and a decrease in share-based compensation expense. Excluding share-based expenses, the increase of research and development personnel expenses would be 23.3%.
- A decrease of 2.7% in sub-contracting, collaborations and consultant costs, primarily attributable to expenses related to the completion of the manufacturing of industrial machines and clinical trials we conducted in 2018, including PEPITES, MILES and SMILEE.
- An increase of 19% of other research and development costs, mainly from depreciation related to the commissioning of our industrial machines (ES GEN 4.0).

*General and Administrative Expenses*

General and administrative expenses were €41.4 million in 2018, compared to €35.8 million in 2017, or an increase of 15.5%.

Our general and administrative expenses are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| | (thousands of Euros) | |
| Personnel expenses | 19,742 | 19,101 |
| Fees | 10,347 | 12,718 |
| Insurance policies | 1,367 | 1,930 |
| Corporate communication and travel expenses | 1,599 | 1,576 |
| Rental | 584 | 911 |
| Depreciation and amortization | 422 | 1,720 |
| Others | 1,776 | 3,442 |
| **Total general and administrative expenses** | **35,837** | **41,399** |

The increase of €5.6 million in general and administrative expenses was primarily due to:

- an increase of 22.9% in fees primarily associated with advisor and consultant fees incurred in 2018 to support the implementation of our new information system, as well as an increase in legal and corporate communications fees; and
- an increase in expenses related to our corporate communications and investor relations efforts.

Those increases were partially offset by:

- a decrease of 3.2% in total general and administrative payroll resulting from the decrease in share-based compensation expense which was partially offset by the increase of employee from 44 in 2017 to 54 in 2018. Excluding the share-based expense, the increase of general and administrative employee-related expenses was 29.5%.

*Sales and Marketing Expenses*

During the period presented, our sales and marketing expenses increased up to €32.2 million in 2018, compared to €15.8 million in 2017, or an increase of 103.3%. Sales and marketing expenses primarily include payroll for the U.S. employees, as well as fees related to pre-commercialization activities for Viaskin® Peanut in North America.

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| | (thousands of Euros) | |
| Personnel expenses | 6,976 | 12,553 |
| Fees | 2,480 | 5,148 |
| Marketing, tradeshows and travel expenses | 5,984 | 14,021 |
| Others | 384 | 446 |
| **Total sales and marketing expenses** | **15,824** | **32,169** |

Our direct sales and marketing expenses consist principally of personnel expenses and market research consultant fees.

The increase of 80.0% in total payroll associated with sales and marketing results primarily from both an increase in headcount and the recruitment of key executives during the second half of 2018, including the recruitment of our new Chief Commercial Officer in July 2018. Excluding share-based expenses, the increase in our sales and marketing employee-related expenses was 79.8%. Our full-time employees dedicated to sales and marketing increased from 11 employees at the end of 2017 to 23 employees at the end of 2018.

The overall increase in sales and marketing expenses also resulted from an increase in marketing costs of €8.0 million and an increase of €2.7 million for professional fees. The increase in expenses are due in part to the expenses and infrastructure linked with the preparation of the launch, if approved, of Viaskin® Peanut in North America.

*Financial (Loss) Profit*

Our net financial result is profit of €0.1 million in 2018 compared to a loss of €2.7 million in 2017. This item includes capital gains on the disposals of investment securities, foreign exchange gains and expenses related to the discounting of the OSEO and BPI advances.

The change in the financial result is mainly due to the recognition in 2017 of an unrealized exchange loss of €2.4 million on intra-group loans denominated in U.S. dollars against an unrealized exchange loss of €0.3 million in 2018.

**B. Liquidity and Capital Resources**

We have financed our operations since our inception through several private placements of equity securities totaling €38.7 million, a €40.6 million initial public offering of our ordinary shares on Euronext Paris in 2012, a €29.9 million PIPE in 2013, of which we received net proceeds of €15.1 million and our shareholders received net proceeds of €14.8 million, and a €104.5 million global offering of both ADSs on Nasdaq and ordinary shares on Euronext Paris, of which we received net proceeds of €93.7 million. In July 2015, we completed a €255.3 million underwritten public offering of 4,140,000 ordinary shares in the form of 8,280,000 ADSs from which we received net proceeds of €237.3 million. In connection with our 2015 public offering, our share capital increased by €414 thousand with a corresponding increase of €236.9 million in our share premium. In March 2018, we completed an underwritten global offering of an aggregate of 4,056,914 ordinary shares in (i) a public offering of 1,600,817 ordinary shares in the form of 3,201,634 ADSs in the United States, Canada and certain other countries outside Europe and (ii) a concurrent private placement of 2,456,097 ordinary shares in Europe (including France), from which we received gross proceeds of €140.8 million. In connection with our 2018 public offering, our share capital increased by €0.4 million with a corresponding increase of €140.4 million in our share premium, gross.

The table below summarizes our sources and uses of cash for the years ended December 31, 2016, 2017 and 2018.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (thousands of Euros) | | |
| Net cash flow used in operating activities | (59,538) | (114,314) | (136,621) |
| Net cash flow used in investing activities | (8,300) | (7,834) | (8,641) |
| Net cash flow provided by financing activities | 1,666 | 286 | 130,676 |
| **Net increase (decrease) in cash and cash equivalents** | **(66,173)** | **(121,863)** | **(14,586)** |

***Cash Used in Operating Activities***

Our net cash flows used in operating activities were €136.6 million, €114.3 million and €59.5 million in 2018, 2017 and 2016, respectively.

During 2018, our net cash flows used in operating activities increased due to the expenses to support the launch and commercialization of Viaskin® Peanut in North America.

During 2017 and 2016, our net cash flows used in operating activities increased due to our advances in our research and development programs. This increase was partially offset in 2016 by a positive change in working capital of €19.0 million over the period.

***Cash Used in Investing Activities***

Our net cash flows used in investing activities were €8.6 million, €7.8 million and €8.3 million in 2018, 2017 and 2016, respectively.

During 2018, our net cash flows used in investing activities increased due to a €3.5 million pledge of securities which was partially offset by the decrease of investment in industrial machines due to the finalization of our two main industrial machines' setup in 2018.

During 2017, our net cash flows used in investing activities were primarily related to the purchase of materials for the engineering and manufacturing of our industrial machines, including the development of a commercial-scale version of our electrospray manufacturing tool, ES GEN4.0, to support the development of our product candidates.

During 2016, net cash flows used in investing activities increased due to the expansion of our corporate headquarters in Montrouge, France, and purchase of tools and equipment for the design, development and manufacturing of industrial machines.

***Cash Provided by Financing Activities***

Our net cash flows resulting from financing activities increased to €130.7 million in 2018 from €0.2 million in 2017 and from €1.7 million in 2016, mainly as a result of our underwritten global offering in 2018.

Consistent with customary practice in the French securities market, we entered into a liquidity agreement (*contrat de liquidité*) with Natixis on April 13, 2012. The liquidity agreement complies with applicable laws and regulations in France. The liquidity agreement authorizes Natixis to carry out market purchases and sales of our shares on Euronext Paris. As of December 31, 2018, we have contributed an aggregate of €0.4 million to the liquidity account. The amount is classified in other non-current financial assets in our statement of financial position. At December 31, 2018, 41 159 shares and €0.4 million were in the liquidity account. The liquidity agreement has a term of one year and will renew automatically unless otherwise terminated by either party.

*Cash and Funding Sources*

During 2018, we obtained new financing on the public markets by issuance of securities.

| | Equity capital | Bank Loans | Other debt | Total |
|---|---|---|---|---|
| | | (thousands of Euros) | | |
| 2016 | — | — | — | — |
| 2017 | — | — | — | — |
| 2018 | 140,815.5 | — | — | 140,815.5 |
| **Total** | **140,815.5** | **—** | **—** | **140,815.5** |

We have incurred net losses each year since our inception. Substantially all of our net losses resulted from costs incurred in connection with our development programs and from general and administrative expenses associated with our operations.

We have not incurred any bank debt. Other debt is comprised of conditional advances which are detailed as follows.

We benefited from multiple conditional advances from OSEO, which advances do not accrue interest and are repayable at 100% in the event of technical and/or commercial success of our product, as determined solely and subjectively by OSEO, a non-refundable subsidy from OSEO, a conditional advance from COFACE and an interest-free loan by Bpifrance.

As of December 31, 2018, we had one advance contract with OSEO Innovation and one grant from BpiFrance Financement remaining.

The agreement with COFACE terminated on December 31, 2016, generating an exceptional income of €146 thousand corresponding to allowances which could not be reimbursed along with our takings, and which therefore remain acquitted to us.

The 3rd OSEO advance: In 2011, we obtained a conditional advance by OSEO for a total amount of €640,000 to finance the development of our programs to treat CMPA. This amount has been fully received, with a first payment of €256,000 in December 2011, a second payment of €256,000 in June 2013 and remaining €128,000 balance paid in January 2014. If the program is deemed to be technically or commercially successful, as determined by OSEO in its sole and subjective discretion it will be repaid in 16 quarterly installments defined as follows: four payments of €64,000 starting on September 30, 2014, then 12 payments of €32,000 starting on September 30, 2015, until June 30, 2018. If this project is deemed to be a technical failure, we will still be obligated to repay OSEO the amount of €256,000. The agreement with OSEO terminated on June 30, 2018.

The 4th OSEO advance: In 2013, we obtained a conditional advance by OSEO for a total amount of €3.2 million in the context of a research and clinical development collaborative project in the field of house dust mites allergies in young children. We refer to this development program as the ImmunaVia project. €903,500 was received in April 2013, €864,989 was received in January 2015. The €918,000 we expected in October 2015 and €481,162 we expected in April 2018 will not be founded. In addition, we received from OSEO a total of €1,919,056 in the form of a non-refundable subsidy. Following the defection of a sponsor, the Immunavia project was interrupted in September 2017. We are required to reimburse the remaining amounts of conditional advances. This reimbursement has been rescheduled in 13 monthly repayments, commencing on May 31, 2018, through May 31, 2019.

The Bpifrance interest-free loan: In 2014, we obtained an interest-free loan from Bpifrance Financement in the amount of €3.0 million to support the pharmaceutical development of Viaskin® Milk. This assistance was received in a single disbursement in November 2014. The planned repayment is scheduled in 20 quarterly repayments of €150,000 each, commencing on June 30, 2017.

The activity for the conditional advances recorded during 2016, 2017 and 2018 is summarized in the table below:

| | 3rd OSEO contract | 4th OSEO contract | BPI advance | COFACE | Total |
|---|---|---|---|---|---|
| **Balance sheet debt as at 12/31/2015** | **318** | **1,669** | **2,666** | **156** | **4,809** |
| Receipts | — | — | — | — | — |
| Repayments | (128) | — | — | (147) | (275) |
| Other transactions | 2 | 16 | 85 | (9) | 95 |
| **Balance sheet debt as at 12/31/2016** | **192** | **1,684** | **2,751** | **0** | **4,628** |
| Receipts | — | — | — | — | — |
| Repayments | (128) | — | (450) | — | (578) |
| Other transactions | 1 | 16 | 84 | — | 101 |
| **Balance sheet debt as at 12/31/2017** | **64** | **1,700** | **2,386** | **0** | **4,150** |
| Receipts | — | — | — | — | — |
| Repayments | (64) | (1,136) | (600) | — | (1,800) |
| Other transactions | — | 60 | 69 | — | 129 |
| **Balance sheet debt as at 12/31/2018** | **—** | **624** | **1,854** | **—** | **2,479** |

(1) The changes in "other transactions" are comprised of the effect of discounting conditional advances.

**Operating Capital Requirements**

As of December 31, 2018, we had €122.8 million in cash and cash equivalents compared to €137.9 million of cash and cash equivalents as of December 31, 2017. We have incurred operating losses and negative cash flows from operations since inception, incurred a net loss of €166.1 million during the year ended December 31, 2018, and have an accumulated deficit and reserves of €254.9 million as of December 31, 2018. Net cash used in operating activities was €136.6 million for the year ended December 31, 2018 and €114.3 million for the year ended December 31, 2017.

We have primarily funded these losses through equity financings. To date, we have not generated any product revenue and we continue to prepare for the potential launch of our Viaskin® Peanut product candidate in North America planned in 2020 for which its BLA submission to the US FDA is expected in the third quarter of 2019. We expect operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support our operating plan for the next 12 months despite additional funds raised in March 2018. We expect to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding our ability to continue as a going concern.

We expect to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

Our financial statements have been prepared on a going concern basis assuming that we will either be successful in our financing objectives. As such, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should we be unable to continue as a going concern.

For more information as to the risks associated with our future funding needs, see the section titled "Item 3.D—Risk Factors."

**Capital Expenditures**

As all the clinical research and development expenditures are posted to the accounts as expenses until marketing authorizations are obtained, the principal investments made over 2016, 2017 and 2018 have been related primarily to the acquisition of laboratory equipment and, secondarily, to the acquisition of computer and office equipment.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (thousands of Euros) | | |
| Intangible assets | (215) | (299) | (41) |
| Property, plant, and equipment | (7,992) | (7,246) | (4,710) |
| Non-current financial assets | (93) | (289) | (3,890) |
| **Total** | **(8,300)** | **(7,834)** | (8,641) |

In 2016, the increase results primarily from

- the buildout of Montrouge, Bagneux and Summit premises for €2.4 million;
- the purchase of tools and equipment for the design, development and manufacturing of industrial machines such as Gen 4.0 and Cut Pack for €3.2 million;
- the purchase of laboratory, clinical and other validation equipment for €1.9 million.

In 2017, the increase results primarily from the purchase of tools and equipment for the design, development and manufacturing of industrial machines.

In 2018, the increase results primarily from the purchase of tools and equipment for the design, development and manufacturing of industrial machines. Those investments significantly decreased in 2018 due to the finalization of our two main industrial machines' setup. Investments also increased in 2018 due to a €3.5 million pledge of securities, which was disclosed as non-current financial assets.

### C. Research and Development

For a discussion of our research and development activities, see "Item 4.B—Business Overview" and "Item 5.A—Operating Results."

### D. Trend Information

For a discussion of trends, see "Item 4.B—Business Overview," "Item 5.A—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

### E. Off-Balance Sheet Arrangements

During the periods presented, we did not and do not currently have any off-balance sheet arrangements as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

### F. Tabular Disclosure of Contractual Obligations

The following table discloses aggregate information about material contractual obligations and periods in which payments were due as of December 31, 2018. Future events could cause actual payments to differ from these estimates.

| | Less than One year | 1 to 3 years | 3 to 5 years | More than 5 years | Total |
|---|---|---|---|---|---|
| | (thousands of Euros) | | | | |
| Financial debt | 1,201 | 1,278 | — | — | 2,479 |
| Capital (finance) lease obligations | — | — | — | — | — |
| Operating lease obligations | 3,965 | 12,169 | 6,996 | 7,137 | 30,267 |
| Purchase obligations | — | — | — | — | — |
| Other long-term liabilities | — | 3,462 | 529 | 114 | 4,105 |
| **Total** | **5,166** | **16,909** | **7,525** | **7,251** | **36,851** |

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including interest on long-term debt, fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

Our corporate headquarters are located in Montrouge, France. Our principal offices occupy a 4,770 square meter facility consisting of office and laboratory space, pursuant to a lease agreement dated March 3, 2015, which expires on March 8, 2024. We also have two facilities in Bagneux, France. These facilities consist of 2,237 square meters of office and laboratory space and are used primarily by our industrial and production teams. In April 2018, we entered into an addendeum to our lease for an additional 500 square meters of office space in building B of Green Square, Bagneux, France. These facilities are leased under one agreement, which expires on May 31, 2020. We entered into an additional lease for offices in Montrouge, France in June 2018. This facility consists of 1,808 square meters of office space, pursuant to a lease agreement dated July 1, 2018, which expires on June 30, 2027. We also have an office in North America to support our U.S. subsidiary as well as future commercialization needs. We lease 3,780 square feet of office space in Tower 49, New York, New York. This lease is for a period of 65 months and expires on February 25, 2023.

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

### G. Safe Harbor

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See "Special Note Regarding Forward-Looking Statements."

## Item 6. Directors, Senior Management and Employees.

### A. Directors and Senior Management.

The following table sets forth information regarding our executive officers and directors, including their ages, as of March 31, 2019. Unless otherwise stated, the address for our executive officers and directors is 177-181 avenue Pierre Brossolette, 92120 Montrouge, France.

| Name | Age | Position(s) |
|---|---|---|
| ***Executive Officers:*** | | |
| Daniel Tassé | 59 | Chief Executive Officer and Director |
| David Schilansky | 43 | Deputy Chief Executive Officer and Chief Financial Officer |
| Laurent Martin | 51 | Deputy Chief Executive Officer and Responsible Pharmacist |
| Dr. Hugh Sampson | 70 | Chief Scientific Officer and interim Chief Medical Officer |
| Pascale Ehouarn | 45 | Chief Engineering, Manufacturing and Supply Officer |
| Susanna Mesa | 33 | Chief Business Officer |
| Magali Richard | 37 | Chief Strategy Officer |
| Sébastien Robitaille | 49 | Chief Transformation Officer and Deputy Chief Financial Officer |
| Joan Schmidt | 55 | Chief Legal Officer |
| Kevin Trapp | 52 | Chief Commercial Officer |
| ***Non-Employee Directors:*** | | |
| Michel de Rosen[3] | 69 | Non-Executive Chairman of the Board of Directors |

| | | |
|---|---|---|
| Dr. Torbjörn Bjerke[1][2][3] | 56 | Director |
| Maïlys Ferrère[3] | 56 | Director |
| Claire Giraut[1] | 62 | Director |
| Michael J. Goller[2][3] | 44 | Director |
| Julie O'Neill | 53 | Director |
| Daniel Soland[1][2] | 60 | Director |

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating committee.

**Executive Officers:**

***Daniel Tassé*** has served as Chief Executive Officer since November 2018 and as a member of our board of directors since March 2019. From March 2016 to November 2018, Mr. Tassé served as the Chairman and Chief Executive Officer of Alcresta Therapeutics, Inc., a pediatric-focused rare disease biotechnology company. From January 2008 to April 2015, Mr. Tassé served as the Chairman and Chief Executive Officer of Ikaria, Inc., which develops drugs and devices for critically ill patients. In April 2015, Ikaria was acquired by Mallinckrodt Pharmaceuticals. Mr. Tassé holds a B.Sc. in Biochemistry from Université de Montréal.

***David Schilansky*** has served as our Deputy Chief Executive Officer since December 2017, and is responsible for enabling effective coordination of our operational and strategic imperatives and overseeing our Executive Committee. Mr. Schilansky has also served as our Chief Financial Officer since December 2011. Mr. Schilansky previously served as our Chief Operating Officer from January 2015 to December 2017. From 2006 to 2011, Mr. Schilansky held various senior positions at the Ipsen Group, or Ipsen, including serving as its Interim Chief Financial Officer, Deputy Chief Financial Officer, a member of Ipsen's Executive Committee and other positions in the administration and finance department and participated in various external growth operations and creation of Ipsen's investor relations function. From 2003 to 2006, Mr. Schilansky spent three years at Thomson Inc. (now Technicolor S.A.) as co-head of investor relations. From 1999 to 2002, he spent three years at Warburg Dillon Read (now UBS Investment Bank) in the field of mergers and acquisitions. Mr. Schilansky received a master's degree from Université de Paris Dauphine and a master's degree from Imperial College in London.

***Laurent Martin*** has served as our Chief Development Officer from January 2016 to March 2019. Mr. Martin has also served as our Deputy Chief Executive officer and Responsible Pharmacist (Qualified Person) since March 2017. He has held various positions since joining us in 2007, including serving as our Senior Executive Vice President, Product Strategy & Regulatory Affairs and Director of Regulatory Affairs and Quality. He acquired his expertise in regulatory affairs through various pharmaceutical companies, such as Galderma, Guerbet and Orphan Europe, a company specialized in the development and marketing of orphan drugs, in which his last position was as Interim Responsible Pharmacist (Qualified Person), Manager of Pharmaceutical and Pre-Clinical Development and Quality Assurance Manager. He received his Pharm.D. from the Université René Descartes in Paris with an M.B.A. from IAE Paris Sorbonne and a Master of Law in Public Health from the faculty of Sceaux.

***Dr. Hugh A. Sampson*** has served as our Chief Scientific Officer since November 2015 and is a member of our Scientific Advisory Board. Dr. Sampson has also served as our interim Chief Medical Officer since January 2019. Dr. Sampson has been a member of our Executive Committee since January 2017. Dr. Sampson is also the Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai and Director Emeritus of the Jaffe Food Allergy Institute. He continues to direct his NIH-funded translational research activities and to see patients in clinical practice. In his role as Chief Scientific Officer, Dr. Sampson leads our research team, pursuing potential new applications of Viaskin® for the treatment of food allergies, while also supporting our clinical development teams. Dr. Sampson is past chair of the Section on Allergy & Immunology of the American Academy of Pediatrics and the past-president of the American Academy of Allergy, Asthma and Immunology. He received his M.D. from the State University of New York at Buffalo School of Medicine and his allergy/immunology fellowship at Duke University.

***Pascale Ehouarn*** has served as our Chief Engineering, Manufacturing & Supply Officer since December 2017, and is responsible for all manufacturing and supply chain processes, including supervision of Viaskin® Peanut's manufacturing tool, GEN.4.0. Ms. Ehouarn is a member of the Executive Committee. She has held various positions since joining us in 2006 and has played an instrumental role in designing our electrospray technology and scaling it up to commercial capacity. Previously, Ms. Ehouarn served as a Research and Development Project Manager at Unaxis, a Switzerland-based provider of semi-conductor thin film coating equipment by plasma. Ms. Ehouarn holds a Ph.D. in Plasma Physics from the University of Paris XI and completed a post-doctorate at the University of Karlsruhe in Germany.

***Susanna Mesa*** has served as our Chief Business Officer since December 2017, and oversees strategic positioning and capital markets, including investor relations and corporate affairs. Ms. Mesa is a member of our Executive Committee. Since joining us in 2014, Ms. Mesa has played an instrumental role in defining and implementing our global strategy. During her tenure as Vice President of Finance, Investor Relations & Strategy, Ms. Mesa was tasked with expanding our shareholder base and supporting our listing on the Nasdaq Stock Market in 2014. Ms. Mesa served as our Senior Vice President of Strategy from April 2016 to December 2017. Prior to joining us, Ms. Mesa served as an advisor on capital formation and business development opportunities at Trout Group. Prior to joining Trout Group, Ms. Mesa held positions at the Leukemia and Lymphoma Society and at Jefferies. Ms. Mesa holds a Bachelor's degree from the University of Georgia.

***Magali Richard*** has served as our Chief Strategy Officer since December 2017, and assists in the definition and implementation of strategic objectives, oversees business development and strategic planning. Ms. Richard is a member of our Executive Committee. Ms. Richard joined us in October 2016 and has been responsible for Business Development and Portfolio Strategy. Prior to joining us, Ms. Richard served as Principal and a member of the Biopharma Practice at the Boston Consulting Group, or BCG. Prior to BCG, Ms. Richard was a scientist at Biomarin Pharmaceutical. Ms. Richard graduated from Ecole Polytechnique in Paris and from Ecole Nationale des Mines de Paris. She also holds a Ph.D. in Molecular Biology from Université Pierre & Marie Curie in France.

***Sebastien Robitaille*** has served as our Chief Transformation Officer and Deputy Chief Financial Officer since December 2017, and is responsible for leading our operational transformation from a development-stage biotechnology company to a potential commercial organization. Mr. Robitaille oversees Finance, Information Systems at Group level and Human Resources in France, and is a member of our Executive Committee. Mr. Robitaille joined us in 2015 as Senior Vice President, Group Controller & Information Systems. Prior to joining us, Mr. Robitaille worked at Ipsen for 15 years, where he held various roles of increasing responsibility and participated in Ipsen's initial public offering. Mr. Robitaille holds a Bachelor's Degree in Business Administration-Finance from Paris School of Business.

***Joan Schmidt*** has served as our Chief Legal Officer since June 2018, and is responsible for leading our legal, compliance and intellectual property functions. Ms. Schmidt is a member of our Executive Committee. From July 2015 to May 2018, Ms. Schmidt served as Executive Vice President, Legal & Human Resources, US, General Counsel and Secretary at Biotronik, Inc., an international medical device company. From September 2003 to May 2015, Ms. Schmidt held various positions of increasing responsibility at Novo Nordisk A/S, and most recently served as Corporate Vice President, Legal Affairs. Ms. Schmidt earned a J.D. from Pace University and a B.A. from the University of Connecticut.

***Kevin Trapp*** has served as our Chief Commercial Officer since August 2018. He is a member of the Executive Committee. As our Chief Commercial Officer, he is responsible for all of our commercial operations globally. Prior to joining us, from 2017 to 2018, Mr. Trapp served as an advisor to us. From 2014 to 2016, he served as Senior Vice President, Portfolio & Access Strategy at Bristol-Myers Squibb Company. Mr. Trapp earned a bachelor's degree from the University of Connecticut School of Business and completed the General Management Program from CEDEP at INSEAD, Fontainebleau, France.

**Non-Employee Directors:**

***Dr. Torbjörn Bjerke*** has served as a member of our board of directors since 2006. Dr. Bjerke is currently the portfolio manager of Arctic Aurora LifeScience and a director of TXP Pharma GmbH, SynAct Pharma and Hatt et Saner. He previously served as the Chief Executive Officer of Karolinska Development AB from 2011 to 2014.

Prior to then, Dr. Bjerke was the President and Chief Executive Officer of Orexo AB, a position he held from 2007 until January 2011, President and Chief Executive Officer of Biolipox AB and Director of Pharmacology at AstraZeneca. Dr. Bjerke holds a Ph.D. in Medicine from Aarhus Universitet. The board of directors believes that Dr. Bjerke's experience in the pharmaceutical industry, particularly his extensive experience in allergy treatment field, and his years of business and leadership experience allow him to make valuable contributions to the board of directors.

***Michel de Rosen*** has served as a member of our board of directors since May 2018 and as Non-Executive Chairman of our board of directors since March 2019. Mr. Rosen also serves on the board of directors of Faurecia and Pharnext. Mr. de Rosen served as Chairman and Chief Executive Officer of Eutelsat from 2009 until his retirement in 2017, Chairman and Chief Executive Officer of ViroPharma from 2000 to 2008, and Chairman and Chief Executive Officer of Rhone-Poulenc Santé from 1993 to 1999. He has also held numerous positions at the French Ministries of Finance, Defense, Industry and Telecommunication. The board of directors believes that Mr. de Rosen's extensive business experience in the biopharmaceutical industry and over 15 years' experience in the United States will be instrumental to the success of our objectives. Mr. Rosen holds an M.B.A. from HEC and an M.B.A. from Ecole Nationale d'Administration.

***Maïlys Ferrère*** has served as a member of our board of directors since 2016 and previously served as a non-voting observer of our board of directors since our initial public offering on Euronext Paris in March 2012. Ms. Ferrère is a Director, Head of the Large Venture Investment Activity at Bpifrance, France's public investment bank, and is affiliated with one of our significant shareholders. She graduated from Institut d'Etudes Politiques Paris, and began her career with the General Inspectorate of Société Générale before working for multiple French banks in the equity capital markets origination department. The board of directors believes that Ms. Ferrère's experience in the banking industry and her knowledge of capital markets allow her to make valuable contributions to the board of directors.

***Claire Giraut*** has served as a member of our board of directors since 2016. From 2013 until her retirement in 2018, Ms. Giraut served as the Executive Vice President, Chief Financial Officer of bioMérieux, a global leader in in vitro diagnostics. She previously served as Chief Financial Officer of Ipsen from 2003 to 2011 and as Chief Financial Officer of Europcar, after holding various finance leadership positions in other worldwide organizations. Since 2010, she has also served as a director of Julius Baer Group Ltd. and Bank Julius Baer & Co. Ltd., a Swiss private banking group. Ms. Giraut holds a master's degree from the Institut National Agronomique (AgroParisTech) in Paris. The board of directors believes that Ms. Giraut's experience in the life sciences industry and her knowledge of financial matters allow her to make valuable contributions to the board of directors.

***Michael J. Goller*** has served as a member of our board of directors since 2015. Mr. Goller serves as a Partner of Baker Brothers Investments, a fund management company focused on long-term investments in life-sciences companies. Prior to joining Baker Brothers in 2005, Mr. Goller was an associate of JPMorgan Partners, LLC where he focused on venture investments in the life sciences sector from 1999 to 2003. Mr. Goller began his career as an investment banker with Merrill Lynch and Co. from 1997 to 1999. Mr. Goller holds a B.S. in Molecular and Cell Biology from The Pennsylvania State University, and a Masters in both Biotechnology and Business Administration from the University of Pennsylvania. The board of directors believes that Mr. Goller's experience in the life sciences industry and his knowledge of corporate development matters allow him to make valuable contributions to the board of directors.

***Julie O'Neill*** has served as a member of our board of directors since 2017. From 2015 to 2018, Ms. O'Neill was served as the Executive Vice President, Global Operations for Alexion Pharmaceuticals Inc. From 2014 to 2015, Ms. O'Neill was Senior Vice President of Global Manufacturing Operations and General Manager of Alexion Pharma International Trading. Prior to joining Alexion, Ms. O'Neill served in various leadership positions at Gilead Sciences from 1997 to 2014 including Vice President of Operations and General Manager of Ireland from 2011 to 2014. Prior to Gilead Sciences, Ms. O'Neill held leadership positions at Burnil Pharmacies and Helsinn Birex Pharmaceuticals. She is the Chairperson for the National Standards Authority of Ireland and is a member of the Boards of the National Institute for Bioprocessing Research & Training and the American Chamber of Commerce, Ireland. Ms. O'Neill received a Bachelor of Science in Pharmacy from University of Dublin, Trinity College and a Masters of Business Administration from University College Dublin (Smurfit School of Business). The board of directors believes that Ms. O'Neill's experience in the life sciences industry and her knowledge of corporate development matters allow her to make valuable contributions to the board of directors.

***Daniel Soland*** has served as a member of our board of directors since 2015. Mr. Soland most recently served as Senior Vice President and Chief Operating Officer of Viropharma, and currently serves on the board of directors of Acadia Pharmaceuticals Inc. In addition to his role at Viropharma, where he helped build the organizational and commercial infrastructure that resulted in an 11-fold increase in Viropharma's share price during his tenure, Mr. Soland previously served as President of Chiron Vaccines, and helped engineer a turnaround that contributed to Chiron's acquisition by Novartis. Prior to then, he served as President and Chief Executive Officer of Epigenesis Pharmaceuticals. At GlaxoSmithKline Biologicals, Mr. Soland served as Vice President and Director, Worldwide Marketing Operations. Earlier in his career, Mr. Soland held positions of increasing responsibility in sales and product management at Pasteur-Merieux's Connaught Laboratories. He holds a B.S. in Pharmacy from the University of Iowa. The board of directors believes that Mr. Soland's extensive executive and management experience in the pharmaceutical industry worldwide, notably at various senior commercial operations positions, allow him to make valuable contributions to the board of directors.

**Family Relationships**

There are no family relationships among any of our executive officers or directors.

**B. Compensation.**

The aggregate compensation recorded and benefits in kind granted by us to our current executive officers and directors, including share-based compensation, for the year ended December 31, 2018, was €17.5 million. For the year ended December 31, 2018, €0.4 million of the amounts set aside or accrued to provide pension, retirement or similar benefits to our employees was attributable to our executive officers.

***Director Compensation***

On March 24, 2015, upon recommendation of our compensation committee, our board of directors set attendance fees for our non-employee directors at a fixed annual retainer of €30,000 per year, regardless of whether or not the director is independent. The members of our audit committee and compensation committee, regardless of whether or not the director is independent, are each entitled to an additional retainer of €5,000 per year. This amount will be increased to €10,000 per year for the chairman of said committees.

On December 9, 2016, upon recommendation of our compensation committee, our board of directors approved an amendment to our non-executive director compensation policy to set attendance fees for our non-employee directors at a fixed annual retainer of €70,000 per year, regardless of whether or not the director is independent. Under the proposed revised policy, the chairman of the audit committee will be entitled to an additional retainer of €20,000 per year, the chairman of the compensation committee will be entitled to an additional retainer of €10,000 per year, and the other members of our audit committee and compensation committee, regardless of whether or not the director is independent, will each be entitled to an additional retainer of €5,000 per year.

On June 15, 2017, our shareholders at our ordinary shareholders' general meeting set the total annual attendance fees to be distributed among non-employee directors at €600,000, which is then distributed according to the amended non-executive director compensation policy. Shareholder authorization for total attendance fees is automatically renewed each year, unless otherwise decided by our shareholders at an ordinary shareholders' general meeting.

On November 16, 2018, we announced the appointment of Daniel Tassé as our Chief Executive Officer and the retirement of Pierre-Henri Benhamou as our Chief Executive Officer.

On November 28, 2018, upon recommendation of our compensation committee, our board of directors decided to allocate to Dr. Benhamou a fixed annual compensation of € 150,000 for his functions of Chairman of the Board of Directors.

On December 12, 2018, upon recommendation of our compensation committee, our board of directors approved an amendment to our non-executive director compensation policy to set attendance fees for the members of our nominating committee at a fixed annual retainer of €10,000 per year to the chairman of the nominating committee and €5,000 per year to the other members, regardless of whether or not the director is independent.

On March 5, 2018, we announced the appointment of Daniel Tassé as Board member in replacement of Dr. Pierre-Henri Benhamou. We also announced the appointment of Michel De Rosen as our Non-executive Chairman and the resignation of Pierre-Henri Benhamou as our Non-executive Chairman.

The following table sets forth information regarding the compensation earned by our non-employee directors for 2018.

| Name | Fees Earned | Warrants (thousands of Euros) | Total |
|---|---|---|---|
| Pierre-Henri Benhamou[1] | 12.5 | | 12.5 |
| Torbjörn Bjerke | 90 | 63.1[3] | 153.1 |
| Michel de Rosen[2] | 48.8 | 81.2[3] | 130.0 |
| Maïlys Ferrère | — | — | — |
| Claire Giraut | 90 | 63.1[3] | 153.1 |
| Michael J. Goller | 85 | 63.1[3] | 148.1 |
| Julie O'Neil | 70 | 63.1[3] | 133.1 |
| Daniel Soland | 130[4] | 63.1[3] | 193.1 |

(1) Dr. Benhamou did not receive additional compensation for his services as a director while he served as our Chief Executive Officer. Following his resignation as our Chief Executive Officer in November 2018, Dr. Benhamou received compensation for his services as a non-executive director. His compensation while serving as our Chief Executive Officer is disclosed under the section below titled "CEO, Former CEO, Deputy CEO and CDO Compensation." On November 28, 2018, the board of directors decided to allocate to Dr. Benhamou a fixed annual compensation of €150,000 for his service as our non-executive chairman of our board of directors, paid monthly. Dr. Benhamou resigned from the board of directors effective March 5, 2019.

(2) Mr. de Rosen was appointed to the board of directors on May 2, 2018.

(3) This column reflects the full grant date fair value for warrants granted during 2018 as measured pursuant to IFRS 2—Share-Based Payment as share-based compensation in our financial statements. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 17 to our financial statements included in this Annual Report on Form 20-F.

(4) Includes a lump sum of €45,000 for a consulting services.

***CEO, Former CEO, Deputy CEO and CDO Compensation***

The following table sets forth information regarding compensation earned by Mr. Daniel Tassé, our Chief Executive Officer and director, Dr. Benhamou, our former Chief Executive Officer, Mr. Schilansky, our Deputy Chief Executive Officer, and Mr. Martin, our former Chief Development Officer, during the year ended December 31, 2018.

| Name and Principal Position | Salary € | Bonus € | Equity Awards € | Non-Equity Incentive Plan Compensation € | Special Compensation € | Total € |
|---|---|---|---|---|---|---|
| Daniel Tassé | | | | | | |
| *Chief Executive Officer and Director*[1] | 47,698 | — | 4,094,832 | — | — | 4,142,530 |
| Pierre-Henri Benhamou | | | | | | |
| *Former Chief Executive Officer*[2] | 468,839[4] | — [5] | 1,716,000 | — | 21,774[6] | 2,206,613 |
| David Schilansky | | | | | | |
| *Deputy Chief Executive Officer* | 375,595 | — [7] | 1,716,000 | — | 62,718[8] | 2,154,312 |
| Laurent Martin | | | | | | |
| *Former Chief Development Officer*[3] | 200,394 | — [9] | 686,400 | — | 31,117[10] | 917,911 |

(1) Mr. Tassé was appointed as our Chief Executive Officer in November 2018 and as a member of our board of directors in March 2019.
(2) Dr. Benhamou resigned as our Chief Executive Officer in November 2018.
(3) Mr. Martin resigned as our Chief Development Officer in March 2019.
(4) Includes €456,339 compensation for Dr. Benhamou's service as our Chief Executive Officer until November 29, 2018 and €12,500 for his duties as Chairman of our board of directors since November 2018.
(5) No bonus was awarded to Dr. Benhamou for 2018 following a decision of our board of directors on February 2019.
(6) A one-time bonus was granted to Dr. Benhamou by our board of directors in December 2017 in recognition of the completion of the March 2018 underwritten global offering. The payment of this special compensation is subject to the approval of our shareholders at the ordinary shareholders' general meeting to be held in May 2019.
(7) No bonus was awarded to Mr Schilansky for 2018 following a decision of our board of directors on February 2019.
(8) Includes (i) a special compensation of €35,501, granted to Mr. Schilansky by our board of directors in December 2017 in recognition of the completion of the March 2018 underwritten global offering and (ii) one additional month of salary in the amount of €27,217, which was granted by our board of directors to all of our employees in October 2018.
(9) No bonus was awarded to Mr Martin for 2018 following a decision of our board of directors on February 2019.
(10) Includes (i) a special compensation of €16,596, granted to Mr. Martin by our board of directors in December 2017 in recognition of the completion of the March 2018 underwritten global offeringand (ii) one additional month of salary in the amount of €14,521, which was granted by our board of directors to all of our employees in October 2018.

***Executive Compensation Arrangements***

For a discussion of our employment arrangements with our executive officers, see "Item 7.B—Related Party Transactions—Arrangements with Our Directors and Executive Officers." Except the arrangements described in "Item 7.B—Related Party Transactions—Arrangements with Our Directors and Executive Officers," there are no arrangements or understanding between us and any of our other executive officers providing for benefits upon termination of their employment, other than as required by applicable law.

**Limitations on Liability and Indemnification Matters**

Under French law, provisions of by-laws that limit the liability of directors are prohibited. However, French law allows sociétés anonymes to contract for and maintain liability insurance against civil liabilities incurred by any of their directors and officers involved in a third-party action, provided that they acted in good faith and within their capacities as directors or officers of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We maintain liability insurance for our directors and officers, including insurance against liability under the Securities Act and we intend to enter into agreements with our directors and executive officers to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements will provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified directors and executive officers.

These agreements may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and executive officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these insurance agreements.

Certain of our non-employee directors may, through their relationships with their employers or partnerships, be insured against certain liabilities in their capacity as members of our board of directors.

**Equity Incentives**

We believe that our ability to grant incentive awards is a valuable and necessary compensation tool that allows us to attract and retain the best available personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, historically, we have granted several different equity incentive instruments to our directors, executive officers, employees and other service providers. These are:

- employee warrants (otherwise known as bons de souscription de parts de créateurs d'entreprise, or BSPCE), granted to our officers and employees;
- non-employee warrants (otherwise known as bons de souscription d'actions, or BSA), historically typically granted only to non-employee directors, members of our Scientific Advisory Board and other service providers not eligible for either employee warrants or employee share options;
- employee share options (otherwise known as options de souscription d'actions, or OSA), granted to our officers and employees; and
- free shares (otherwise known as actions gratuites).

Our board of directors' authority to grant these equity incentive instruments and the aggregate amount authorized to be granted must be approved by a two-thirds majority of the votes held by our shareholders present, represented or voting by authorized means at the relevant extraordinary shareholders' meeting. Once approved by our shareholders, our board of directors can continue to grant such awards for 18 months for employee warrants and non-employee warrants authorized by the shareholders and 38 months for employee share options and free shares authorized by the shareholders.

We are no longer eligible to issue employee warrants since completion of our initial public offering on Euronext Paris in 2012.

In general, employee warrants, employee share options and non-employee warrants no longer continue to vest following termination of the employment, office or service of the holder and all vested shares must be exercised within post-termination exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants or share options.

As of December 31, 2018, employee warrants, non-employee warrants, employee share options and free share were allowing for the purchase of an aggregate of 3,366,296 ordinary shares at a weighted average exercise price of €41.55 per share (not including the 572,228 ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price being paid).

***Employee Warrants (BSPCE)***

Employee warrants were granted only to our employees who are French tax residents as they carry favorable tax and social security treatment for French tax residents. Employee warrants may also be granted to our chairman and general manager and to our deputy general managers. Similar to options, they entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary share on the date of grant. Employee warrants may only be issued by growth companies meeting certain criteria, which we will not meet following the completion of the offering. There is no legal limitation to the size of the employee warrant (BSPCE) pool under French law.

We have issued three types of employee warrants as follows:

| **Plan title** | **BSPCE 4** | **BSPCE X** | **BSPCE 2010** | |
|---|---|---|---|---|
| Meeting date | 1/21/2009 | 1/21/2009 | 12/16/2010 | |
| Date of allocation by the Board of Directors | 1/21/2009 | 1/21/2009 | 6/24/2011 | 11/22/2011 |
| Total number of BSPCE authorized | 5,358 | 10,858 | 59,405 | 59,405 |
| Total number of BSPCEs granted | 5,358 | 2,296 | 24,000 | 10,039 |
| *including those granted to Pierre-Henri Benhamou* | — | — | 10,000 | — |
| Start date for the exercise of the BSPCEs | 1/21/2009 | 1/21/2010 | 12/23/2011 | 11/22/2012 |
| BSPCE expiry date | 1/21/2019 | 1/21/2019 | 6/24/2021 | 11/22/2021 |
| BSPCE exercise price[(1)] | € 4.33 | € 4.67 | € 5.13 | € 5.13 |
| Number of shares subscribed as of December 31, 2018[(1)] | 80,370 | 34,440 | 252,510 | 150,585 |
| Total number of BCPCEs canceled or obsolete as of December 31, 2018 | — | — | — | — |
| Total number of BCPCEs outstanding as of December 31, 2018 | — | — | 7,166 | — |
| Total number of shares available for subscription as of December 31, 2018[(1)] | — | — | 107,490 | — |

(1) The number of shares reflects an adjusted exercise parity of the division by 15 of the nominal value of the shares decided by the general meeting of shareholders held on December 9, 2011, namely that each BPSCE is now entitled to a subscription right to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BPSCE plan has been adjusted accordingly and equals 1/15 of the price initially determined by the general meeting of shareholders having authorized each of the plans.

All BPSCE 4, BPSCE X and BSPCE 2010 granted on June 2011 and BSPCE 2010 granted on November 2011 are exercisable.

***Administration.*** Pursuant to delegations granted by our shareholders, our board of directors determined the recipients, dates of grant and exercise price of employee warrants, the number of employee warrants to be granted and the terms and conditions of the employee warrants, including the period of their exercisability and their vesting schedule. The board of directors has the authority to extend the post-termination exercise period of employee warrants after the termination of the employment agreement.

Employee warrants are not transferable and may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by laws of descent or distribution and may be exercised, during the lifetime of the beneficiary, only by the beneficiary.

***Non-Employee Warrants (BSA)***

Historically, non-employee warrants were typically granted by our board of directors to non-employee directors, members of our Scientific Advisory Board and other service providers not eligible for either employee warrants or employee share options. In addition to any exercise price payable by a holder upon the exercise of any non-employee warrant, non-employee warrants need to be subscribed for a price which is determined by the board on the date of grant. There is no legal limitation to the size of the non-employee warrant pool.

We have issued several types of non-employee warrants (BSAs) as of December 31, 2018, the terms of which are set forth in the chart below:

| Plan title | BSA | BSA 2 | BSA X | | BSA 2010 | | | | BSA 2012 | BSA 2013 | BSA 2014 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Meeting date | 6/14/2007 | 1/21/2009 | 1/21/2009 | | 12/16/2010 | | | | 12/9/2011 | 6/4/2013 | 6/3/2014 |
| Date of grant by the Board of Directors | 12/7/2007 | 1/21/2009 | 1/21/2009 | 6/25/2010 | 1/28/2011 | 6/24/2011 | 11/22/2011 | 1/17/2012 | 9/25/2012 | 7/25/2013 | 6/3/2014 |
| Total number of BSAs authorized | 4,395 | 10,716 | 10,858 | 10,858 | 59,405 | 59,405 | 59,405 | 59,405 | 300,000 | 100,000[2] | 307,468 |
| Total number of BSAs granted | 1,717 | 10,716 | 306 | 1,825 | 10,039 | 8,000 | 1,338 | 89,835[3] | 30,000 | 73,000 | 10,000 |
| Including those granted to Pierre-Henri Benhamou | — | 5,358 | — | — | — | — | — | — | — | — | — |
| *Torbjørn Bjerke* | 859 | — | 306 | 730 | — | — | — | — | 2,500 | 2,500 | 2,500 |
| Start date for the exercise of the BSAs | 12/7/2008 | 1/21/2009 | 1/21/2010 | 6/25/2011 | 12/23/2011 | 12/23/2011 | 11/22/2012 | 1/17/2016 | 9/25/2013 | 7/25/2013 | 6/3/2014 |
| BSA expiry date | 12/7/2017 | 1/21/2019 | 1/21/2019 | 6/25/2020 | 1/28/2021 | 6/24/2021 | 11/22/2021 | 1/17/2022 | 9/25/2022 | 7/25/2023 | 6/3/2024 |
| BSA exercise price | € 4.33 | € 4.33 | € 4.33 | € 4.33 | € 5.13 | € 5.13 | € 5.13 | € 5.13 | € 8.59 | € 8.10 | € 18.79 |
| Number of shares subscribed as of December 31, 2018 | 17,175[1] | 160,740[1] | 4,590 | 27,375[1] | 37,650[1] | 112,500[1] | 20,070[1] | 89,835 | 25,000 | 66,000 | 10,000 |
| Total number of BSAs canceled or obsolete as of December 31, 2018 | 572 | — | — | — | 7,529 | — | — | — | — | — | — |
| Total number of BSAs remaining as of December 31, 2018 | — | — | — | — | — | 500 | — | — | 5,000 | 7,000 | — |
| Total number of shares available for subscription as of December 31, 2018[1] | — | — | — | — | — | 7,500 | — | — | 5,000 | 7,000 | — |

(1) The number of shares reflects an adjusted exercise parity of the division by 15 of the nominal value of shares. Namely, each BSA is now entitled to a subscription right to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BSA plan has been adjusted accordingly and equals 1/15 of the price initially determined.
(2) The overall nominal amount of the shares to which the warrants issued are likely to give entitlement may not exceed €100,000.
(3) The number of BSAs reflects an adjusted exercise parity of the division by 15 of the nominal value of shares.

| Plan Title | BSA 2015 | | BSA X 2015 | BSA 2016 | | BSA 2017 |
|---|---|---|---|---|---|---|
| General Meeting Date | 06/03/14 | 06/23/15 | 06/23/15 | 06/21/16 | 06/21/16 | 06/15/17 |
| Date of the Grant by the Board of Directors | 03/24/15 | 11/19/15 | 12/15/15 | 06/21/16 | 12/09/16 | 06/15/17 |
| Total Numbers of BSA's granted | 10,000 | 22,500 | 90,000[1] | 20,000 | 59,000[2] | 9,000 |
| *included those granted to:* | | | | | | |
| *Torbjørn Bjerke* | — | 7,500 | — | — | 7,000 | — |
| *Daniel Soland* | 10,000 | 7,500 | — | — | 7,000 | — |
| *Michael Goller* | — | — | 7,500 | — | 7,000 | — |
| *Claire Giraut* | — | — | — | 10,000 | — | — |
| *Julie O'Neill* | — | — | — | — | — | 9,000 |
| Start date of the exercise of the BSAs | 03/24/15 | 11/19/15 | 12/15/15 | 06/21/16 | 12/09/16 | 06/15/17 |
| BSA expiry date | 03/24/25 | 11/19/25 | 12/15/25 | 06/21/26 | 12/09/26 | 06/15/27 |
| BSA exercise price | € 43.00 | € 66.06 | € 64.14 | € 52.97 | € 69.75 | € 59.05 |
| Numbers of shares subscribed as of December 31, 2018 | — | — | — | — | — | — |
| Total number of BSAs cancelled or obsolete as of December 31, 2018 | — | 7,500 | 16,500[1] | — | 24,992 | — |
| Total number of BSAs remaining as of December 31, 2018 | 10,000 | 15,000 | 73,500 | 20,000 | 34,008 | 9,000 |
| Total number of shares available for subscription as of December 31, 2018 | 10,000 | 15,000 | 73,500 | 20,000 | 34,008 | 9,000 |

(1) The final subscription date for the BSAs issued in December 2015 was February 15, 2016; none of these BSAs were subscribed as of December 31, 2015. At February 15, 2016, 73,500 BSAs were subscribed and 16,500 BSAs were cancelled.

(2) The final subscription date for the BSAs issued in December 2016 was February 9, 2017; none of these BSAs were subscribed as of December 31, 2016. At February 9, 2017, 34,008 BSAs were subscribed.

All BSA, BSA 2, BSA X and BSA 2010 are currently exercisable. All BSA 2012, 2013, 2014 2015 and BSA X 2015 are exercisable subject to continuous membership of our Board or Scientific Advisory Board (as the case may be) and subject to applicable insiders' rules.

***Administration.*** Pursuant to delegations granted by our shareholders, our board of directors determined the recipients, dates of grant and exercise price of non-employee warrants, the number of non-employee warrants to be granted and the terms and conditions of the non-employee warrants, including the period of their exercisability and their vesting schedule. The board of directors has the authority to extend the post-termination exercise period of non-employee warrants after the end of the term of office.

Non-employee warrants may be transferred to any person and may be exercised by their holder at any time subject to vesting.

***Share Options (OSA)***

We have granted share options to our employees and our officers pursuant to our 2013 Share Option Plan, or 2013 Plan, our 2014 Share Option Plan, or 2014 Plan, our 2015 Share Option Plan, or 2015 Plan, our 2016 Share Option Plan, or 2016 Plan, our 2017 Share Option Plan, or 2017 Plan and our 2018 Share Option Plan, or 2018 Plan. Our current plan, the 2018 Plan, was adopted by our board of directors on June 21, 2018.

Share options may be granted to any individual employed by us or by any affiliated company under the terms and conditions of an employment contract. Employee share options may also be granted to our chairman and general manager and to our deputy general managers and are subject to the fulfillment of certain performance conditions.

The maximum number of our ordinary shares that may be issued pursuant to share options granted under the 2013 Plan, 2014 Plan, 2015 Plan, 2016 Plan, 2017 Plan and 2018 Plan are 518,000, 75,000, 315,000, 359,060, 998,500 and 817,000, respectively. In addition, under French law, the maximum number of shares issuable upon exercise of outstanding employee share options may not exceed one-third of the outstanding share capital on a non-diluted basis as at the date of grant.

| **Plan title** | **SO 2013** | **SO 2014** | **SO 2015** | | |
|---|---|---|---|---|---|
| Meeting date | 12/09/2011 | 06/03/2014 | 06/03/2014 | 06/03/2014 | 06/03/2014 |
| Date of allocation by the board of directors | 9/18/2013 | 06/03/2014 | 6/23/2015 | 09/30/2015<br>11/19/2015 | 12/15/2015<br>01/04/2016 |
| Total number of options granted | 518,000 | 75,000 | 120,000 | 195,000 | 75,000 |
| *Including those granted to Pierre-Henri Benhamou* | 129,000(2) | — | — | — | — |
| *David Schilansky* | (4) | — | — | — | — |
| *Laurent Martin* | (5) | — | — | — | — |
| Start date for the exercise of options(1) | 9/19/2017 | 06/04/2016 | 6/24/2016(3) | 11/19/2016(3) | 01/04/2017(3) |
| Options expiry date | 9/18/2023 | 06/03/2024 | 6/24/2026 | 11/19/2025 | 01/04/2026 |
| Options exercise price | € 7.57 | € 19.01 | € 48.90 | € 66.06 | € 65.68 |
| Number of shares subscribed as of December 31, 2018 | 268,000 | 35,000 | — | — | — |
| Total number of options canceled or obsolete as of December 31, 2018 | 47,000 | — | — | 25,000 | — |
| Total number of options remaining as of December 31, 2018 | 203,000 | 40,000 | 120,000 | 170,000 | 75,000 |
| Total number of shares available for subscription as of December 31, 2018 | 203,000 | 40,000 | 120,000 | 170,000 | 75,000 |

(1) By way of exception, in the event of a change in control (as defined in Article L.233-3 of the French Commercial Code) all of the options could be exercised in advance.

(2) Our board of directors has set at 10% the number of acquired shares that must be kept by Dr. Benhamou in registered form until the cessation of his duties.

(3) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 25% of the SO as of 26 months after the grant date; (iii) up to an additional 25% of the SO as of 36 months after the grant date; and (iv) up to an additional 25% of the SO as of 48 months after the grant date.

(4) Mr. Schilansky was appointed to serve as our Executive Vice President by our board of directors on December 16, 2014 as of January 8, 2015. Only the plans granted since his appointment are mentioned in this section.

(5) Mr. Martin was appointed to serve as our Executive Vice President and Responsible Pharmacist (Qualified Person) by our board of directors on March 14, 2017. Only the plans granted since his appointment are mentioned in this section.

| Plan Title | SO 2016 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Meeting date | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 | 03/06/14 |
| Date of allocation by the board of directors | 04/06/16 | 04/06/16 | 06/21/16 | 06/21/16 | 06/21/16 | 06/21/16 | 06/21/16 | 12/09/16 | 12/15/16 |
| | 04/21/16 | 05/02/16 | | 08/01/16 | 09/15/16 | 10/17/16 | 11/15/16 | | |
| Total number of options granted | 33,000 | 22,000 | 110,000 | 10,000 | 9,300 | 16,500 | 8,300 | 74,960 | 1,100 |
| *Including those granted to:* | | | | | | | | | |
| *Pierre-Henri Benhamou* | — | — | — | — | — | — | — | — | — |
| *David Schilansky* | — | — | — | — | — | — | — | — | — |
| Start date for the exercise of options | 04/21/17[1] | 05/02/17[1] | 06/21/17[2] | 08/01/17[2] | 09/15/17[2] | 10/17/17[2] | 11/15/17[2] | 12/09/17 | 12/15/17 |
| Options expiry date | 04/21/26 | 05/02/26 | 06/21/26 | 08/01/26 | 09/15/26 | 10/17/26 | 11/15/26 | 12/09/26 | 12/15/26 |
| Options exercise price | € 62.82 | € 59.04 | € 53.96 | € 62.24 | € 62.80 | € 64.39 | € 68.33 | € 69.75 | € 69.35 |
| Number of shares subscribed as of December 31, 2018 | — | — | 1,200 | — | — | — | — | — | — |
| Total number of options canceled or obsolete as of December 31, 2018 | 11,000 | 22,000 | 21,300 | — | — | 7,200 | — | 22,965 | — |
| Total number of options remaining as of December 31, 2018 | 22,000 | — | 87,500 | 10,000 | 9,300 | 9,300 | 8,300 | 51,995 | 1,100 |
| Total number of shares available for subscription as of December 31, 2018 | 22,000 | — | 87,500 | 10,000 | 9,300 | 9,300 | 8,300 | 51,995 | 1,100 |

(1) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 25% of the SO as of 26 months after the grant date; (iii) up to an additional 25% of the SO as of 36 months after the grant date; and (iv) up to an additional 25% of the SO as of 48 months after the grant date.

(2) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 12.5% of the SO as of 18 months after the grant date; (iii) up to an additional 12.5% of the SO as of 26 months after the grant date; (iv) up to an additional 12.5% of the SO as of 30 months after the grant date; (v) up to an additional 12.5% of the SO as of 36 months after the grant date; (vi) up to an additional 12.5% of the SO as of 42 months after the grant date; and (vii) up to an additional 12.5% of the SO as of 48 months after the grant date.

| Plan Title | SO 2017 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Meeting date | 06/03/2014 | 06/03/2014 | 06/03/2014 | 06/03/2014 | 06/15/2017 | 06/15/2017 | 06/15/2017 | 06/15/2017 | 06/15/2017 |
| Date of allocation by the board of directors | 01/16/2017 | 03/15/2017 | 04/18/2017 | 06/15/2017 | 06/15/2017 | 07/17/2017 | 09/15/2017 | 12/05/2017 | 12/15/2017 |
| Total number of options granted | 19,100 | 7,200 | 16,500 | 126,000 | 111,600 | 30,900 | 52,600 | 625,200 | 8,300 |
| *Including those granted to:* | | | | | | | | | |
| *Pierre-Henri Benhamou* | — | — | — | — | — | — | — | — | — |
| *David Schilansky* | — | — | — | — | — | — | — | — | — |
| *Laurent Martin* | — | — | — | — | — | — | — | — | — |
| Start date for the exercise of options | 01/16/2018(1) | 03/15/2018(1) | 04/18/2018(1) | 06/15/2018(1) | 06/15/2018(1) | 07/17/2018(1) | 09/15/2018(1) | 12/05/2018((1) | 12/15/2018((1) |
| Options expiry date | 01/16/2027 | 03/15/2027 | 04/18/2027 | 06/15/2027 | 06/15/2027 | 07/17/2027 | 09/15/2027 | 12/05/2027 | 12/15/2027 |
| Options exercise price | € 66.11 | € 66.25 | € 60.77 | € 59.05 | € 60.54 | € 71.61 | € 74.22 | € 39.00 | € 38.18 |
| Number of shares subscribed as of December 31, 2018 | — | — | — | — | — | — | — | — | — |
| Total number of options canceled or obsolete as of December 31, 2018 | — | — | 9,300 | 35,000 | — | 23,700 | 7,200 | 85,125 | — |
| Total number of options remaining as of December 31, 2018 | 19,100 | 7,200 | 7,200 | 91,000 | 111,600 | 7,200 | 45,400 | 540,075 | 8,300 |
| Total number of shares available for subscription as of December 31, 2018 | 19,100 | 7,200 | 7,200 | 91,000 | 111,600 | 7,200 | 45,400 | 540,075 | 8,300 |

(1) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 12.5% of the SO as of 18 months after the grant date; (iii) up to an additional 12.5% of the SO as of 26 months after the grant date; (iv) up to an additional 12.5% of the SO as of 30 months after the grant date; (v) up to an additional 12.5% of the SO as of 36 months after the grant date; (vi) up to an additional 12.5% of the SO as of 42 months after the grant date; and (vii) up to an additional 12.5% of the SO as of 48 months after the grant date.

| **Plan Title** | SO 2018 | | | | SO 2018 | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Meeting date | 06/15/2017 | 06/15/2017 | 06/15/2017 | 06/15/2017 | 06/22/2018 | 06/22/2018 | 06/22/2018 | 06/22/2018 | 06/22/2018 |
| Date of allocation by the board of directors | 01/15/2018 | 04/16/2018 | 05/15/2018 | 06/15/2018 | 06/22/2018 | 07/16/2018 | 08/15/2018 | 09/6/2018 | 09/15/2018 |
| Total number of options granted | 15,500 | 16,500 | 16,500 | 23,600 | 50.000 | 28,800 | 33,500 | 65,000 | 80,900 |
| *Including those granted to:*: | | | | | — | | | | |
| Pierre-Henri Benhamou | — | — | — | — | — | — | — | — | — |
| David Schilansky | — | — | — | — | — | — | — | — | — |
| Laurent Martin | — | — | — | — | — | — | — | — | — |
| Start date for the exercise of options | 01/15/2019(1) | 04/16/2019(1) | 05/15/2019(1) | 15/06/2019(1) | 06/22/2019(1)(2) | 07/16/2019(1)(2) | 08/15/2019(1)(2) | 09/06/2019(1)(2) | 09/15/2019(1)(2) |
| Options expiry date | 01/15/2028 | 04/16/2028 | 05/15/2028 | 06/15/2028 | 06/22/2028 | 07/16/2028 | 08/15/2028 | 09/6/2028 | 09/15/2028 |
| Options exercise price | € 43.60 | € 38.64 | € 40.84 | € 38.92 | € 37.22 | € 33.81 | € 32.90 | € 36.96 | € 40.94 |
| | | | | | | | | 96 | |
| Number of shares subscribed as of December 31, 2018 | — | — | — | — | — | — | — | — | — |
| Total number of options canceled or obsolete as of December 31, 2018 | 7,200 | — | — | — | — | — | — | — | — |
| Total number of options remaining as of December 31, 2018 | 8,300 | 16,500 | 16,500 | 23,600 | 50,000 | 28,800 | 33,500 | 65,000 | 80,900 |
| Total number of shares available for subscription as of December 31, 2018 | **8,300** | **16,500** | **16,500** | **23,600** | **50,000** | **28,800** | **33,500** | **65,000** | **80,900** |

(1) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 12.5% of the SO as of 18 months after the grant date; (iii) up to an additional 12.5% of the SO as of 26 months after the grant date; (iv) up to an additional 12.5% of the SO as of 30 months after the grant date; (v) up to an additional 12.5% of the SO as of 36 months after the grant date; (vi) up to an additional 12.5% of the SO as of 42 months after the grant date; and (vii) up to an additional 12.5% of the SO as of 48 months after the grant date.

(2) The exercise of these options will be subject to the fulfillment of a presence condition and the following performance condition: authorization to market Viaskin® Peanut by the FDA.

| Plan Title | SO 2018 | | | | |
|---|---|---|---|---|---|
| **Meeting date** | 06/22/2018 | 06/22/2018 | 06/22/2018 | 06/22/2018 | 06/22/2018 |
| **Date of allocation by the board of directors** | 10/15/2018 | 11/15//2018 | 11/29/2018 | 12/12/2018 | 12/15/2018 |
| **Total number of options granted** | 76,700 | 26,000 | 350,000 | 34,000 | 7,200 |
| ***Including those granted to*:** | | | | | |
| Daniel Tassé | — | — | 350,000 | — | — |
| Pierre-Henri Benhamou | — | — | — | — | — |
| David Schilansky | — | — | — | — | — |
| Laurent Martin | — | — | — | — | — |
| **Start date for the exercise of options** | 10/15/2019[(1)(2)] | 11/15/2019[(1)(2)] | 11/29/2019[(1)(2)] | 12/12/2019[(2)(3)] | 12/15/2019[(2)(3)] |
| **Options expiry date** | 10/15/2028 | 11/15/2028 | 11/29/2028 | 12/12/2028 | 12/15/2028 |
| **Options exercise price** | € 37.28 | € 32.57 | € 30.02 | € 27.96 | € 26.76 |
| **Number of shares subscribed as of December 31, 2018** | — | — | — | — | — |
| **Total number of options canceled or obsolete as of December 31, 2018** | — | — | — | — | — |
| **Total number of options remaining as of December 31, 2018** | **76,700** | **26,000** | **350,000** | **34,000** | **7,200** |
| **Total number of shares available for subscription as of December 31, 2018** | **76,700** | **26,000** | **350,000** | **34,000** | **7,200** |

(1) The SOs may be exercised by the beneficiary on the basis of the following vesting schedule: (i) up to 25% of the SO as of one year after the grant date; (ii) up to an additional 12.5% of the SO as of 18 months after the grant date; (iii) up to an additional 12.5% of the SO as of 26 months after the grant date; (iv) up to an additional 12.5% of the SO as of 30 months after the grant date; (v) up to an additional 12.5% of the SO as of 36 months after the grant date; (vi) up to an additional 12.5% of the SO as of 42 months after the grant date; and (vii) up to an additional 12.5% of the SO as of 48 months after the grant date.

(2) The exercise of these options will be subject to the fulfillment of a presence condition and the following performance condition: authorization to market Viaskin® Peanut by the FDA.

***Administration.*** Our board of directors has the authority to administer the 2013 Plan, 2014 Plan, 2015 Plan, 2016 Plan, 2017 Plan and 2018 Plan, or collectively, the Plans. Subject to the terms of each of the Plans, our board of directors determines recipients, dates of grant, exercise price of share options, the number of share options to be granted and the terms and conditions of the share options, including the period of their exercisability and their vesting schedule.

The board of directors has the authority to modify awards outstanding under the Plans subject to the consent of the optionee if such modification is detrimental to him/her, including in particular the authority to extend the post-termination exercise period after the termination of the employment.

The term of each share option is ten years from the date of grant or, in the case of death or disability of the optionee during such ten-year period, six months from the death or disability of the optionee in accordance with French law. In the event of the death of an optionee during the term of the options, unless otherwise resolved by the board of directors, the vested options may be exercised at any time within six months following the date of death, by the optionee's estate or by a person who acquired the right to exercise the option by bequest or inheritance.

Share options are not transferable and may not be sold, pledged, assigned, hypothecated, transferred or disposed of in any manner other than by will or by laws of descent or distribution and may be exercised, during the lifetime of the optionee, only by the optionee.

***Amendment and Termination.*** Our board of directors has the authority to amend, alter, suspend, or terminate the Plans, provided that such action does not impair the rights of any optionee without such optionee's consent. We shall obtain shareholder approval of any amendment to the extent necessary and desirable to comply with applicable laws.

***Free Shares***

Under our 2012, 2013, 2014, 2015, 2016, 2017 and 2018 Free Share Plans, we have granted free shares to our employees and officers. We have seven current free share plans, including a 2015 Free Share Plan, which was adopted by our board of directors on September 30, 2015, a 2015 Free Share Plan, which was adopted by our board of directors on December 15, 2015, a 2016 Free Share Plan, which was adopted by our board of directors on April 6, 2016, a 2016 Free Share Plan, which was adopted by our board of directors on October 27, 2016, a 2017 Free Share Plan, which was adopted by our board of directors on March 14, 2017, a 2017 Free Share Plan, which was adopted by our board of directors on April 20, 2017 and a 2018 Free Share Plan, which was adopted by our board of directors on June 22, 2018.

Free shares may be granted to any individual employed by us or by any affiliated company under the terms and conditions of an employment contract. Free shares may also be granted to our Chairman, our general manager and to our deputy general managers. However, no free share may be granted to a beneficiary holding more than 10% of our share capital or to a beneficiary who would hold more than 10% of our share capital as a result of such grant.

***Share Reserve.*** The maximum number of our ordinary shares that may be issued, in aggregate, under the 2017 and 2018 Free Share Plans is 572,228. In addition, under French law, the number of free shares may not exceed 10% of the outstanding share capital on a non-diluted basis as at the date of grant.

The details of the grants under the 2015, 2016, 2017 and 2018 Free Share Plans as of December 31, 2018 are as follows:

**INFORMATION REGARDING FREE SHARES**

| Plan Title | Free share Plan 2015 | |
|---|---|---|
| General meeting date | 09/21/15 | 09/21/15 |
| Date of grant by the board of directors | 09/30/15 | 12/15/15 |
| Total number of free shares granted | 708,500 | 42,000 |
| Including those granted to: | | |
| • *Pierre-Henri Benhamou* | 120,000 | — |
| • *David Schilansky*[2] | 80,000 | — |
| • *Laurent Martin*[8] | (4) | (4) |
| Date of definitive acquisition of free shares (subject to the conditions of acquisition)[1] | 09/30/17[3] | 12/15/17[3] |
| End date of retention period[2] | 09/30/17 | 12/15/17 |
| Number of shares acquired definitively as of December 31, 2018 | 685,500 | 33,000 |
| Cumulative number of free shares canceled or lapsed as of December 31, 2018 | 23,000 | 9,000 |
| Shares acquired free of charge remaining as of December 31, 2018 (in acquisition period) | — | — |

(1) In the event of incapacity of a beneficiary as defined in Article L. 225-197-1, I of the French Commercial Code during the vesting period, said beneficiary may request the allocation of the shares within a period of six months from the event that led to the incapacity. In the event of the death of a beneficiary during the vesting period, his heirs may request the free allocation of shares within a period of six months from the death.

(2) Mr. Schilansky was appointed to serve as our Executive Vice President by our board of directors on December 16, 2014 as of January 8, 2015. Only the plans granted since his appointment are mentioned in this section.

(3) The acquisition of free shares is conditional for executive officers, including Dr. Benhamou, to the achievement of the three performance criteria below:

- One-third of the shares allocated to executive officers will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from 9/30/2015 and (ii) the achievement of the primary efficacy endpoint of the Phase III PEPITES trial for Viaskin® Peanut.
- One-third of the shares allocated to executive officers will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from 9/30/2015 and (ii) the achievement of the primary efficacy endpoint of the Phase II MILES trial for Viaskin® Milk.
- One-third of the shares allocated to executive officers will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from 9/30/2015 and (ii) the beginning of clinical testing of another product candidate from the Viaskin® platform.

(4) Mr. Martin was appointed Executive Vice President and Responsible Pharmacist (Qualified Person) by our board of directors on March 14, 2017. Only the plans granted since his appointment are mentioned in this section.

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**INFORMATION REGARDING FREE SHARES**

| Plan Title | Free Share Plan 2016 | | | | | | |
|---|---|---|---|---|---|---|---|
| General meeting date | 09/21/15 | 09/21/15 | 09/21/15 | 09/21/15 | 09/21/15 | 09/21/15 | 09/21/15 |
| Date of grant by the board of directors | 04/06/16 | 06/21/16 | 06/21/16 | 06/21/16 | 10/27/16 | 12/09/16 | 12/09/16 |
| Total number of free shares granted | 63,750 | 193,000 | 10,000 | 5,000 | 15,000 | 13,600 | 10,000 |
| Including those granted to: | | | | | | | |
| *Pierre-Henri Benhamou* | — | 30,000 | — | — | — | — | — |
| *David Schilansky* | — | 20,000 | — | — | — | 100 | — |
| *Laurent Martin*[5] | (5) | (5) | (5) | (5) | (5) | (5) | (5) |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Date of definitive acquisition of free shares (subject to the conditions of acquisition) [1] | 04/06/18[1] | 06/21/18[1] | 08/16/18[1] | 09/01/18[1] | 10/27/18[2] | 12/09/18[3] | 12/09/18[2] |
| End date of retention period | 04/06/18[4] | 06/21/18[4] | 08/16/18[4] | 09/01/18[4] | 10/27/18[4] | 12/09/18[4] | 12/09/18[4] |
| Number of shares acquired definitively as of December 31, 2018 | 57,500 | 193,000 | 10,000 | 5,000 | 15,000 | 10,800 | 9,000 |
| Cumulative number of free shares canceled or lapsed as of December 31, 2018 | 6,250 | — | — | — | — | 2,800 | 1,000 |
| Shares acquired free of charge remaining as of December 31, 2018 (in acquisition period) | — | — | — | — | — | — | — |

(1) The acquisition of free shares is conditional for executive officers, including Dr. Benhamou, to the achievement of the three performance criteria below:

- One-third of the shares allocated will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase III PEPITES trial for Viaskin® Peanut.
- One-third of the shares allocated will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase II MILES trial for Viaskin® Milk.
- One-third of the shares allocated will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the beginning of clinical testing of another product candidate from the Viaskin® platform.

(2) The acquisition of free shares is conditional for employees to the achievement of the two performance criteria below:

- Half of the shares allocated will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase III PEPITES trial for Viaskin® Peanut.
- Half of the shares allocated to executive officers will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase II MILES trial for Viaskin® Milk.

(3) The acquisition of free shares allocated to executive officers is conditional to the achievement of the two performance criteria below:

- Half of the shares allocated will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase III PEPITES trial for Viaskin® Peanut.
- Half of the shares allocated to executive officers will not vest until the later of the following two dates: (i) the end of the two year vesting period which runs from the grant date and (ii) the achievement of the primary efficacy endpoint of the Phase II MILES trial for Viaskin® Milk

(4) No retention period for the Free Share Plans issued in 2016.

(5) Mr. Martin was appointed Executive Vice President and Responsible Pharmacist (Qualified Person) by our board of directors on March 14, 2017. Only the plans granted since his appointment are mentioned in this section.

| **Plan Title** | AGA 2017 | |
|---|---|---|
| General meeting date | 09/21/15 | 09/21/15 |
| Date of grant by the board of directors | 03/14/2017 | 04/20/2017 |
| Total number of free shares granted | 22,500 | 24,000 |
| Including those granted to:: | | |
| • Monsieur Pierre-Henri Benhamou | — | — |
| • Monsieur David Schilansky | — | — |
| • Monsieur Laurent Martin[2] | — | — |
| Date of definitive acquisition of free shares (subject to the conditions of acquisition) [1] | 03/14/19[1] | 04/20/19[1] |

| | | |
|---|---|---|
| End date of retention period | (3) | (3) |
| Number of shares acquired definitively as of December 31, 2018 | — | — |
| Cumulative number of free shares canceled or lapsed as of December 31, 2018 | 5,500 | — |
| Shares acquired free of charge remaining as of December 31, 2018 (in acquisition period) | 17,000 | 24,000 |

(1) The acquisition of free shares is conditional for every employee, to the achievement of the two performance criteria below:

- half of the shares allocated will not vest until the later of the following two dates: (i) the end of the two-year vesting period which runs from the date of the grant and (ii) BLA file accepted for review by the FDA for Viaskin® Peanut.
- half of the shares allocated will not vest until the later of the following two dates: (i) the end of the two-year vesting period which runs from the date of the grant and (ii) the first date of sale of Viaskin® Peanut in the United States.

(2) Mr. Martin was appointed Executive Vice President and Responsible Pharmacist (Qualified Person) by our board of directors on March 14, 2017. Only the plans granted since his appointment are mentioned in this section.

(3) No retention period for the Free Share Plans issued in 2017.

| Plan Title | AGA 2018 | | | | |
|---|---|---|---|---|---|
| General meeting date | 06/22/18 | 06/22/18 | 22/06/18 | 22/06/18 | 22/06/18 |
| Date of grant by the board of directors | 06/22/18 | 09/06/18 | 11/01/18 | 12/12/18 | 12/12/18(3) 12/17/18 |
| Total number of free shares granted | 486,153 | 450 | 57,000 | 16,250 | 3,000 |
| Including those granted to: | | | | | |
| • Monsieur Pierre-Henri Benhamou | 50,000 | — | — | — | — |
| • Monsieur David Schilansky | 50,000 | — | — | — | — |
| • Monsieur Laurent Martin | 20,000 | — | — | — | — |
| Date of definitive acquisition of free shares (subject to the conditions of acquisition) (1) | 06/22/19(1) | 09/06/19(1) | 11/01/19(1) | 12/12/19(1) | 12/17/19(1) |
| End date of retention period | 06/22/21(2) | 09/06/21(2) | 11/01/21(2) | 12/12/21(2) | 12/17/21(2) |
| Number of shares acquired definitively as of December 31, 2018 | — | — | — | — | — |
| Cumulative number of free shares canceled or lapsed as of December 31, 2018 | 21,125 | — | 10,500 | — | — |
| Shares acquired free of charge remaining as of December 31, 2018 (in acquisition period) | 465,028 | 450 | 46,500 | 16,250 | 3,000 |

(1) The definitive allocation of the free shares will only occur at the later of the following two dates, subject to the presence requirement:

(i) expiry of the current acquisition period as from their initial allocation; and

(ii) approval of Viaskin® Peanut by the US Food and Drug Administration (U.S. FDA) (performance condition).

(2) The Board of Directors set a lock-up period of two years from the date of final allotment of the shares, after which the beneficiaries may freely sell the shares.

(3) Notification date of the allocation by the CEO acting on sub-delegation of the Board of Directors, following the beginning of employment

***Administration.*** Our board of directors has the authority to administer the 2017 and 2018 Free Share Plans. Subject to the terms of the plans, our board of directors determines recipients, dates of grant, the number of free shares to be granted and the terms and conditions of the free shares, including the length of their acquisition period (period starting on the date of grant during which the beneficiary holds a right to acquire shares for free but not any shares yet) and holding period (period starting at the end of the acquisition period when the shares are issued and definitively acquired and issued but may not be transferred) within the limit determined by the shareholders (in particular the acquisition period is at least two years from the date of grant for the 2015, 2016 and 2017 Free Shares Plans and one year for the 2018 Free Shares Plan. The holding period is two years from the end of the acquisition period for the 2018 Free Shares Plan. No additional holding period is applicable for the 2015, 2016 and 2017 Free Share Plans).

The board of directors has the authority to modify awards outstanding under our 2012, 2013, 2014, 2015, 2016, 2017 and 2018 Free Share Plans subject to the consent of the beneficiary if such modification is detrimental to him/her, including in particular the authority to release a beneficiary from the continued service condition during the acquisition period after the termination of the employment.

***Free Shares.*** The free shares granted under our 2017 and 2018 Free Share Plans will be definitively acquired at the end of the acquisition period as set by our board of directors subject to continued service during the acquisition period, except if the board releases a given beneficiary from this condition upon termination of his/her employment contract. At the end of the acquisition period, the beneficiary will be the owner of the shares. However, during the holding period under the 2018 Free Share Plan (as set by our board of directors with a minimum of two years except if the acquisition period is at least equal to four years), the shares may not be sold, transferred or pledged. Under the 2015, 2016 and 2017 Free Share Plans, the granted free shares may be sold, subject to the regulations governing companies whose shares are traded on a regulated market, as soon as the shares vest. The free shares allocated to the beneficiaries will be new ordinary shares and will immediately have the same rights as the existing company shares.

In the event of disability before the end of the acquisition period, the free shares shall be definitively acquired by the beneficiary on the date of disability. In the event the beneficiary dies during the acquisition period, the free shares shall be acquired at the date of the request of allocation made by his or her beneficiaries in the framework of the inheritance provided that such request is made within six months from the date of death.

Under the 2017 and 2018 Free Share Plans, in the event of a change of control of the company, the beneficiaries will remain eligible for the allocation at the end of each respective vesting period, even if the beneficiary's employment contract and/or corporate mandate is terminated for any reason, between the date of the takeover and the last day of the vesting period. In this scenario, the shares will automatically vest and are not subject to the achievement of performance criteria.

***Amendment and Termination.*** Our board of directors has the authority to amend, alter, suspend, or terminate our 2017 and 2018 Free Share Plans, provided that such action does not impair the rights of any beneficiary without such beneficiary's consent. The company shall obtain shareholder approval of any amendment to the extent necessary and desirable to comply with applicable laws.

**C. Board Practices.**

We currently have eight directors, less than a majority of whom are citizens or residents of the United States. Under French law and our by-laws, our board of directors must be composed of between three and 18 members. Within this limit, the number of directors is determined by our shareholders. Since January 1, 2017, the number of directors of each gender may not be less than 40%. Any appointment made in violation of this limit that is not remedied will be null and void. Directors are elected, re-elected and may be removed at a shareholders' general meeting with a simple majority vote of our shareholders. Pursuant to our by-laws, our directors are elected for two-year terms. In accordance with French law, our by-laws also provide that our directors may be removed with or without cause by the affirmative vote of the holders of at least a majority of the votes of the shareholders present, represented by a proxy or voting by mail at the relevant ordinary shareholders' meeting, and that any vacancy on our board of directors resulting from the death or resignation of a director, provided there are at least three directors remaining, may be filled by vote of a majority of our directors then in office provided that there has been no shareholders meeting since such death or resignation. Directors chosen or appointed to fill a vacancy shall be elected by the board of directors for the remaining duration of the current term of the replaced director. The appointment must then be ratified at the next shareholders' general meeting. In the event the board of directors would be composed of less than three directors as a result of a vacancy, the remaining directors shall immediately convene a shareholders' general meeting to elect one or several new directors so there are at least three directors serving on the board of directors, in accordance with French law.

The following table sets forth the names of our directors, the years of their initial appointment as directors and the expiration dates of their current term.

| Name | Current Position | Year of Initial Appointment | Term Expiration Year |
|---|---|---|---|
| Daniel Tassé[(1)] | Director | 2019 | 2020 |
| Torbjörn Bjerke | Director | 2006 | 2020 |
| Michel de Rosen[(2)] | Chairman | 2018 | 2020 |
| Maïlys Ferrère | Director | 2016 | 2020 |
| Claire Giraut | Director | 2016 | 2020 |
| Michael J. Goller | Director | 2015 | 2020 |
| Julie O'Neill | Director | 2017 | 2019 |
| Daniel Soland | Director | 2015 | 2020 |

(1) Mr. Tassé was appointed to our board of directors on March 5, 2019 to replace Pierre-Henri Benhamou for the term of its remaining mandate, i.e. until the end of the General Meeting held in 2020.
(2) Mr. de Rosen was appointed to our board of directors on May 2, 2018.

***Director Independence***

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except to the extent that our audit committee is required to consistent of independent requirements, subject to certain phase-in schedules. However, our board of directors has determined that, under current listing requirements and rules of Nasdaq (which we are not subject to) and taking account any applicable committee independence standards, Claire Giraut, Torbjörn Bjerke, Michel de Rosen, and Daniel Soland are "independent directors." In making such determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining the director's independence, including the number of ordinary shares beneficially owned by the director and his or her affiliated entities (if any).

***Role of the Board in Risk Oversight***

Our board of directors is primarily responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

***Corporate Governance Practices***

As a French société anonyme, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to the Nasdaq corporate governance listing standards. However, the Nasdaq Global Select Market's listing standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of the Nasdaq rules, with certain exceptions. We currently rely on the certain exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, including Nasdaq corporate governance rules that state (1) a majority of the board of directors consists of independent directors; (2) establishing a nominating and corporate governance committee; (3) the compensation committee be composed entirely of independent directors; and (4) separate executive sessions of independent directors and non-management directors held by the company at least twice per year.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our general shareholders' meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least 33 $^{1}/_{3}$% of the outstanding shares of the company's common voting stock. Consistent with French law, our by-laws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months. See "Item 10.B—Memorandum and Articles of Association."

Furthermore, we intend to follow French corporate governance practices in lieu of the Nasdaq corporate governance rules that require shareholder approval prior to specified issuances of securities. More specifically, Nasdaq Marketplace Rule 5635 requires a U.S. domestic listed company to obtain shareholder approval: (1) prior to the issuance of securities when the issuance or potential issuance will result in a change of control of the issuer; (2) prior to the issuance of securities in connection with a transaction other than a public

offering involving the sale, issuance or potential issuance by the issuer alone, or together with sales by its officers, directors or substantial shareholders, of common stock (or securities convertible into or exercisable for common stock) equal to 20% or more of the common stock or 20% or more of the voting power outstanding before the issuance for less than the greater of book or market value; and (3) prior to the issuance of securities when an equity compensation arrangement is made or materially amended, including prior to the issuance of common stock to the issuer's officers, director, employees or consultants for less than the greater of book or market value. While French law requires a French company to obtain prior shareholder approval to issue shares, its shareholders may pre-authorize the company's board of directors to issue shares such that shareholder approval is not required at the time of issuance.

For example, during the ordinary and extraordinary general meeting held on June 22, 2018, our shareholders have granted our board of directors the following delegations of authority to issue ordinary shares or other securities giving access to our share capital ("Securities"), in one or more occasions, in the proportions and at the times the board of directors will consider it appropriate, either in euros, or in foreign currencies or in any other unit of account established by reference to a series of currencies:

(1) delegations of authority to increase our share capital by issuing Securities, through rights issues, for the maximum duration permitted under French law (26 months) within a maximum potential dilution equal to 20% of our share capital at the date of the relevant share capital increase for an ordinary share subscription price that shall be freely determined by our board of directors at the time of the issuance;

(2) delegations of authority to increase our share capital by issuing Securities, through public offering or private placement, for the maximum duration permitted under French law (26 months) within a maximum potential dilution equal to 20% of our share capital at the date of the relevant share capital increase (and 10% of our share capital over a 12 months period in case of private placement) for a subscription price that shall be at least equal to the volume weighted average of the closing price of our company's ordinary shares on Euronext Paris for the 3 trading days prior to the pricing, eventually decreased by a maximum discount of 5%;

(3) delegations of authority to increase our share capital by issuing Securities, without preemptive rights, to the benefit of categories of persons meeting certain characteristics, in accordance with the provisions of the French commercial code, for the maximum duration permitted under French law (18 months) within a maximum potential dilution equal to 20% of our share capital at the date of the relevant share capital increase for an ordinary share subscription price that shall be freely determined by our board of directors at the time of the issuance;

(4) delegation of authority to increase our share capital by incorporation of reserves, profits or premium either by the issuance of new shares attributed to each existing shareholder or by the increase of the nominal value per share for a duration of 26 months within a maximum aggregate potential dilution of 50% of our share capital at the date of the relevant share capital increase; and

(5) delegation of authority to increase our share capital by issuing Securities, in view of remuneration of contributions (securities) in kind to our company for a duration of 26 months within a maximum potential dilution equal to 10% of our share capital at the date of the ordinary and extraordinary general meeting held on June 22, 2018.

Please note that:

- in respect of delegations 1 2 and 3, in addition to the above limits, the number of securities to be issued may be increased by 15% of the initial issuance (at the same subscription price of the initial issuance), within the dilution limit set by said general meeting, if an excess of demand is observed, it being noted that such issuance shall be decided during a 30 day period starting from the closing of the subscription period of the initial issuance;
- in respect of delegation 2 above, in the case where the issuance does not exceed 10% of our share capital per year, our board of directors may determine that the subscription price shall be at least equal to, at the choice of our board of directors, either (1) the volume weighted-average of the closing price of our company's ordinary shares on Euronext Paris on the day preceding the determination of the subscription price, eventually decreased by a maximum discount of 15% or (2) the average price of our company's ordinary shares on Euronext Paris for a period of 5 consecutive trading days to be chosen amongst the last thirtieth trading days preceding the determination of the subscription price, eventually decreased by a maximum discount of 15%;
- the overall limit of the nominal amount of shares that can be issued pursuant to the delegations of authority granted to our board of directors as per the above shall not exceed 65% of the share capital at the time of our ordinary and extraordinary general meeting held on June 22, 2018; and
- the board cannot, unless authorized in advance by our shareholders, make use of the above-mentioned delegations during a period of public offering initiated by a third party targeting our securities until the end of the offering period.

Furthermore, during this ordinary and extraordinary shareholders' meeting held on June 22, 2018, our board of directors received the following delegations from the shareholders:

- a delegation of authority to grant share options (options de souscription et/ou d'achat d'actions) to our officers and employees for the maximum duration of 18 months, with a maximum potential dilution equal to 5% of our share capital at the date of the shareholders' meeting, for which delegation our shareholders waived automatically their preferential subscription rights with respect to all such grants.
- a delegation of authority to grant free shares (attribution gratuite d'actions) to our officers and employees within a maximum potential dilution equal to 4.5% of our share capital on the date of such shareholders' meeting, for which delegation our shareholders waived automatically their preferential subscription rights with respect to all such grants. This authorization will apply until the general meeting of shareholders to be held in 2019 to rule on the financial statements of the previous year;
- a delegation of authority to issue equity warrants (bons de souscription d'actions et bons de souscription et/ou d'acquisition d'actions nouvelles et/ou existantes), redeemable equity warrants (bons de souscription et/ou d'acquisition d'actions nouvelles et/ou existantes remboursables), to the benefit of our officers, employees, members of our Scientific Advisory Board and other service providers and/or consultants for the maximum duration of 18 months, within a maximum potential dilution equal to 0.5% of our share capital on the date of such shareholders' meeting, for which delegation our shareholders waived their preferential subscription rights with respect to all such issuances; and
- delegation of authority to increase our share capital by issuing ordinary shares or other securities giving access to our share capital, to the benefit of employees investing in our company saving plan, for a duration of 26 months within a maximum potential dilution equal to 2% of our share capital at the date of the relevant share capital increase, for which delegation our shareholders waived their preferential subscription rights with respect to such all such issuances.

We do not intend to follow Nasdaq Marketplace Rule 5635 with respect to issuances or potential issuances of securities that are within the scope of authorization provided by the ordinary and extraordinary general meeting of shareholders held on June 22, 2018 or by any other subsequent ordinary or extraordinary general meeting of shareholders that may resolve on the same purpose, to our board of directors.

***Board Committees***

The board of directors has established an audit committee and a compensation committee, which operate pursuant to a unique charter adopted by our board of directors. The board of directors has also established a nominating committee. The composition and functioning of all of our committees will comply with all applicable requirements of the French Commercial Code, the Exchange Act, the exchange on which the ADSs are listed, and SEC rules and regulations.

Subject to the following paragraph concerning audit committee, in accordance with French law, committees of our board of directors will only have an advisory role and can only make recommendations to our board of directors. As a result, decisions will be made by our board of directors taking into account non-binding recommendations of the relevant board committee.

***Audit Committee.*** In accordance with French law, the audit committee has the following responsibilities : (i) it monitors the process of preparing the financial information and, where appropriate, makes recommendations to ensure its integrity, (ii) it monitors the efficiency of risk management and internal control systems, as well as that of internal audits if applicable, with regard to the preparation and processing of financial and accounting information, without prejudice to its independence, (iii) it issues a recommendation on the statutory auditors proposed for appointment by the general meeting, (iv) it monitors implementation by the statutory auditors of their mission, (v) it ensures that the statutory auditors comply with independence criteria, (vi) it approves the provision of services other than the auditing of accounts referred to in Article L.822-11-2 of the French Commercial Code, (vii) it reports regularly to the Board on the performance of its tasks. It also reports on the outcome of the accounts auditing task, how this task contributed to the integrity of the financial information, and the role it played in that process. It immediately informs the Board about any difficulties encountered.

Dr. Bjerke, Mr. Soland and Ms. Giraut currently serve on our audit committee. Ms. Giraut is the chairperson of our audit committee. Our board has determined that each of Dr. Bjerke, Mr. Soland and Ms. Giraut is independent within the meaning of the applicable listing rules and the independence requirements contemplated by Rule 10A-3 under the Exchange Act. Our board of directors has further determined that Ms. Giraut is an "audit committee financial expert" as defined by SEC rules and regulations and that each of Mr. Soland and Dr. Bjerke qualifies as financially sophisticated under the applicable exchange listing rules.

Our audit committee has the following responsibilities:

- monitoring the process of preparing the financial information and, where appropriate, make recommendations to ensure its integrity;
- monitoring the efficiency of risk management and internal control systems, as well as that of internal audits if applicable, with regard to the preparation and processing of financial and accounting information, without prejudice to its independence;
- issuing a recommendation on the statutory auditors proposed for appointment by the general meeting. This recommendation to our board of directors is prepared in accordance with the provisions of Article 16 of (EU) Regulation no. 537/2014; it also issues a recommendation to this body when the renewal of the mandate of the auditor(s) is considered.

Except for renewal, the recommendation must be justified and contain at least two choices while stating a reasoned preference. This recommendation is prepared following a selection procedure led by our audit committee. The recommendations and preferences of our audit committee are presented at our general meeting held to determine the appointment of the statutory auditor;

- monitoring implementation by the statutory auditors of their mission and taking account of any findings and conclusions made by the French High Council of Statutory Auditors following controls carried out pursuant to Articles L. 821-9 et seq. of the French Commercial Code;
- ensuring that the statutory auditors comply with independence criteria; where applicable, our audit committee takes the required measures for application of the provisions relating to financial independence set out in Article 4 section 3 of (EU) Regulation no. 537/2014 and ensures compliance with the conditions specified in Article 6 of the same regulation;
- approving the provision of services other than the auditing of accounts referred to in Article L. 822-11-2 of the French Commercial Code; and
- regularly reporting to our board of directors on the performance of its tasks. Our audit committee also reports on the outcome of the accounts auditing task, how this task contributed to the integrity of the financial information and the role it played in that process. Our audit committee immediately informs our board of directors about any difficulties encountered.

In addition to the functions referred to above, our board of directors entrusts the following specific missions to our audit committee:

- with regard to our financial statements:
- to examine and verify our draft budgets and draft annual and interim financial statements before they are sent to the board of director;
- to examine the draft comments, announcements and financial communication concerning our financial statements; and
- to provide a timely opinion to our administrative and financial management upon the latter's request.
- with regard to our cash flow:
- to examine and verify our general cash flow policy (investments and loans, risk hedging tools) and our cash flow situation.
- with regard to the risk management:
- to establish and oversee procedures for the treatment of complaints or submissions identifying concerns regarding accounting, internal accounting controls or auditing matters;
- to examine the state of significant disputes;
- to examine off-balance sheet risks and commitments;
- to examine the relevance of risk monitoring procedures; and
- to review and oversee all related-party transactions in accordance with our Person Transaction Policy. In addition, the audit committee's mission is to provide its opinion on the repayment of the costs incurred by the members of the board of directors on our behalf and to prepare mapping of the legal risks of any kind to which we are exposed.

***Compensation Committee.*** Our compensation committee assists our board of directors in reviewing and making recommendations to our board of directors with respect to the compensation of our executive officers and directors. Dr. Bjerke and Messrs. Goller and Soland currently serve on the compensation committee. Mr. Bjerke is the chairperson of our compensation committee. The principal duties and responsibilities of our compensation committee include:

- proposing all elements of the total compensation, including retirement and provident plans, supplemental retirement plans, benefits in kind, and miscellaneous equity compensation for our executive officers and members of our executive committee;
- being informed by the company on a regular basis of the recruitment of the principal members of the management of the company other than the Chief Executive Officer, as well as review of the initial offer of and all subsequent changes to the elements of management's proposed compensation;
- providing its opinion on the company's broad strategy in terms of compensation policies;

- as applicable, proposing directors' attendance fees to be submitted to the general shareholders' meeting, as well as their appropriate distribution among board members;
- providing its opinion on the principles set by us with regard to profit sharing and shareholding; and
- providing its opinion on funds allocated to board members elected by the employees, if applicable.

***Nominating Committee***. The principal responsibilities of our nominating committee include (i) preparing proposals for the renewal, replacement or appointment of new directors, in consultation with the Chairman of our board of directors, (ii) providing an opinion, with the support of the Chairman of our board of directors, on the appointment or replacement of the Chief Executive Officer and/or the Executive Vice Presidents, as the case may be, as well as the members of the Executive Committee and (iii) establishing, when appropriate, with the agreement of the Chairman of our board of directors, a succession plan for executive corporate officers. Dr. Bjerke, Mr. Goller, Mr. de Rosen and Ms. Ferrère currently serve on the nominating committee.

**D. Employees.**

As of December 31, 2018, we had 315 employees. We consider our labor relations to be good. At each date shown, we had the following employees, broken out by department and geography:

| | At December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| **Function:** | | | |
| Pre-clinical development, quality assurance and regulatory affairs | 31 | 54 | 93 |
| Medical and clinical development | 23 | 44 | 62 |
| Research | 44 | 47 | 19 |
| Engineering and production | 28 | 33 | 38 |
| Management and administration | 31 | 54 | 76 |
| Commercial operations and U.S. marketing | 7 | 12 | 27 |
| Total | 164 | 244 | 315 |
| **Geography:** | | | |
| Australia | 0 | 0 | 5 |
| Canada | 0 | 0 | 1 |
| France | 146 | 209 | 240 |
| United States | 18 | 35 | 69 |
| Total | 164 | 244 | 315 |

**E. Share Ownership.**

For information regarding the share ownership of our directors and executive officers, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

## Item 7. Major Shareholders and Related Party Transactions

**A. Major shareholders.**

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of December 31, 2018 for:

- each beneficial owner of more than five percent (5%) of our outstanding ordinary shares;
- our Chief Executive Officer, Deputy Chief Executive Officer, Chief Financial Officer and Chief Development Officer;
- each of our directors; and
- all of our directors and executive officers as a group. Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares that can be acquired within 60 days of December 31, 2018. The percentage ownership information shown in the table is based upon 30,157,777 ordinary shares outstanding as of December 31, 2018.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding ordinary shares subject to options and warrants held by that person that are immediately exercisable or exercisable within 60 days of December 31, 2018. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders. Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of DBV Technologies S.A., 177-181 avenue Pierre Brossolette, 92120 Montrouge, France.

| | Shares Beneficially Owned | |
|---|---|---|
| | Number | Percentage |
| **5% Shareholders:** | | |
| Entities affiliated with Caisse de Dépôts et Consignations[1] | 3,296,363 | 10.93% |
| Entities affiliated with Baker Bros. Advisors LP[2] | 4,760,466 | 15.77 |
| Morgan Stanley[3] | 1,555,082 | 5.16 |
| Entities affiliated with Boxer Capital, LLC[4] | 2,250,000 | 7.46 |
| Entities affiliated with Perceptive Advisors LLC[5] | 1,636,331 | 5.43 |
| ArrowMark Colorado Holdings, LLC[6] | 1,774,846 | 5.89 |
| **Directors and Executive Officers:** | | |
| Daniel Tassé | — | — |
| David Schilansky | 306,758 | 1.02 |
| Laurent Martin[7] | 150,179 | * |
| Pierre-Henri Benhamou | 711,959 | 2.36 |
| Torbjörn Bjerke[8] | 78,850 | * |
| Michel de Rosen[9] | 32,570 | * |
| Maïlys Ferrère | — | — |
| Claire Giraut[10] | 17,000 | * |
| Michael J. Goller[11] | 21,500 | * |
| Julie O'Neill[12] | 16,000 | * |
| Daniel Soland[13] | 41,500 | * |
| All directors and executive officers as a group (18 persons)[14] | 1,900,364 | 6.17% |

(1) The information shown is based, in part, on a Schedule 13G/A filed by Bpifrance Participations S.A., or BpiP, Innobio FPCI, or Innobio, Bpifrance Investissement S.A.S., or BpiI, Caisse des Dépôts, or CDC, EPIC Bpifrance, or EPIC and Bpifrance S.A., or BPI, on May 7, 2018. Consists of 2,980,230 ordinary shares directly held by BpiP, 226,133 ordinary shares directly held by Innobio and 90,000 ordinary shares directly held by CDC. BpiP is the wholly-owned subsidiary of BPI. CDC and EPIC each hold 50% of the share capital of BPI and jointly control BPI. Innobio is managed by BpiI. BpiI is a wholly-owned, indirect subsidiary of BpiP. Neither BPI, EPIC nor BpiI hold any ordinary shares directly. BpiI may be deemed to be the beneficial owner of 226,133 ordinary shares, through its management of Innobio. BPI may be deemed to be the beneficial owner of 3,178,228 ordinary shares, indirectly through its sole ownership of BpiP, which is the parent company of BpiI. EPIC may be deemed to be the beneficial owners of 3,206,363 ordinary shares, indirectly through its joint ownership and control of BPI. CDC may be deemed to be the beneficial owner of 3,296,363 ordinary shares directly and indirectly through its joint ownership and control of BPI. The principal address for BpiP, BPI, EPIC, Innobio and BpiI is 27-31, avenue du Général Leclerc, 94710 Maisons-Alfort Cedex, France. The principal address for CDC is 56, rue de Lille, 75007 Paris, France.

(2) The information is based solely on a Schedule 13D/A filed by Baker Bros. Advisors LP, Baker Bros. Advisors (GP) LLC, Felix J. Baker and Julian C. Baker on June 26, 2018. Consists of (a) 4,321,936 ordinary shares directly held by Baker Brothers Life Sciences, L.P., (b) 417,030 ordinary shares directly held by 667, L.P. and (c) 21,500 ordinary shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law. Baker Bros. Advisors LP is the investment advisor of each of these funds and has sole voting and investment power with respect to the shares held by Baker Brothers Life Sciences, L.P. and 667, L.P. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. Baker Biotech Capital (GP), LLC is the sole general partner of Baker Biotech Capital, L.P., which is the sole general partner of 667, L.P. The controlling members of Baker Biotech Capital (GP), LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all securities except to the extent of their pecuniary interest. The address for each of these entities is 860 Washington Street, 3rd Floor, New York, New York 10014.

(3) This information is based solely on a Schedule 13G/A filed by Morgan Stanley on February 12, 2019. The principal business address for Morgan Stanley is 1585 Broadway New York, New York 10036.

(4) This information is based solely on a Schedule 13/AG filed by Boxer Capital, LLC, or Boxer Capital, Boxer Asset Management Inc., or Boxer Management, and Joe Lewis on February 14, 2019. Boxer Management is the managing member and majority owner of Boxer Capital. Joe Lewis is the sole indirect beneficial owner of and controls Boxer Management. The principal business address for Boxer Capital is 11682 El Camino Real, Suite 320, San Diego, CA 92130. The principal business address for Boxer Management and Joe Lewis is Cay House, EP Taylor Drive N7776, Lyford Cay, New Providence, Bahamas.

(5) This information is based solely on a Schedule 13G/A filed by Perceptive Advisors LLC, or Perceptive Advisors, Joseph Edelman and Perceptive Life Sciences Master Fund, Ltd., or the Master Fund, on February 14, 2019. The Master Fund directly holds 809,371 ordinary shares and 826,960 ADSs, each representing one-half of one ordinary share. Perceptive Advisors serves as the investment manager to the Master Fund and may be deemed to beneficially own the securities directly held by the Master Fund. Joseph Edelman is the managing member of Perceptive Advisors and may be deemed to beneficially own the securities directly held by the Master Fund. The principal business address for Perceptive Advisors is 51 Astor Place, 10th Floor, New York, New York 10003.

(6) This information is based solely on a Schedule 13G filed by ArrowMark Colorado Holdings, LLC on February 14, 2019. The principal business address for ArrowMark Colorado Holdings, LLC is 100 Fillmore Street, Suite 325, Denver, Colorado 80206.

(7) Consists of (a) 90,189 shares and (b) 59,990 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(8) Consists of (a) 35,925 shares and (b) 42,925 shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(9) Consists of (a) 23,570 shares and (b) 9,000 shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(10) Consists of shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(11) Consists of shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law. Mr. Goller has neither voting nor dispositive power and has no direct pecuniary interest in these securities. He has entered into an agreement with Baker Bros. Advisors LP related to his beneficial ownership of our securities, as disclosed in a Schedule 13D/A filed by Baker Bros. Advisors LP, Baker Bros. Advisors (GP) LLC, Felix J. Baker and Julian C. Baker on June 26, 2018.

(12) Consists of shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(13) Consists of (a) 5,000 shares and (b) 36,500 shares issuable upon the exercise of warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

(14) Consists of (a) 1,280,949 shares and (b) 619,415 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of December 31, 2018, subject to French law.

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2018 are as a result of the March 2018 underwritten global offering, which is described under “Item 7.B—Related Party Transactions—Participation in Underwritten Global Offering” and the dilution resulting from such underwritten global offering. None of our principal shareholders have voting rights different than our other shareholders.

As of December 31, 2018, we estimate that approximately 53% of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held in the United States by 37 holders of record. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

**B. Related Party Transactions.**

Since January 1, 2018, we have engaged in the following transactions with our directors, executive officers and holders of more than five percent (5%) of our outstanding voting securities and their affiliates, which we refer to as our related-parties.

**Participation in Underwritten Global Offering**

As part of our March 2018 underwritten global offering, certain of our holders of more than 5% of our outstanding voting securities and their affiliates purchased an aggregate of 1,728,597 ordinary shares at the public offering price of €34.71 per ordinary share. The following table sets forth the aggregate number of ordinary shares that one of our directors and certain of our holders of more than 5% of our outstanding voting securities and their affiliates purchased:

| Related Party | Number of Ordinary Shares |
|---|---|
| Entities affiliated with Baker Bros. Advisors LP(1) | 1,114,877 |
| Bpifrance Participations S.A.(2) | 584,925 |

(1) Consists of 1,002,478 ordinary shares issued to Baker Brothers Life Sciences, L.P. and 12,399 ordinary shares issued to 667, L.P.
(2) Consists of 584,925 ordinary shares issued to Bpifrance Participations S.A.

**Registration Rights**

In March 2018, we entered into a registration rights agreement, or the Registration Rights Agreement, with entities affiliated with Baker Bros. Advisors LP, or Baker Brothers, pursuant to which Baker Brothers is entitled to rights with respect to the registration under the Securities Act of ordinary shares and ADSs, including ordinary shares or ADSs issuable upon the exercise or conversion of any other securities (whether equity, debt or otherwise) owned or subsequently acquired by Baker Brothers. These rights include demand registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting commissions, will be borne by Baker Brothers. Under the terms of the Registration Rights Agreement, we are required, upon the request of Baker Brothers, to file a registration statement covering, and use our reasonable best efforts to effect, the registration of the ordinary shares, including in the form of ADSs, requested to be registered for public resale. In addition, if we register our securities either for our own account or for the account of other security holders under certain circumstances more than six months following the completion of our March 2018 underwritten global offering, Baker Brothers is entitled to include its ordinary shares or ADSs in such registration. Subject to certain exceptions, we and the underwriters may limit the number of ordinary shares or ADSs included in an underwritten offering conducted pursuant to the terms of the Registration Rights Agreement if the underwriters believe that including such securities would adversely affect the offering. The registration rights granted under the Registration Rights Agreement will terminate ten years after the date of the Registration Rights Agreement.

**Agreements with Our Directors and Executive Officers**

***Employment and Consulting Arrangements***

*Daniel Tassé*

In November 2018, we entered into an executive agreement (as French "*mandataire social*") with Mr. Daniel Tassé, our current Chief Executive Officer. He is entitled to an annual base salary. Mr. Tassé is also eligible to receive equity grants as our board of directors may determine and to participate in our bonus plan.

In December 2018, our board of directors fixed the performance criteria in the event of termination of Mr. Daniel Tassé's duties as our Chief Executive Officer. He will benefit from a severance package if all the following objectives are achieved: (i) Viaskin® Peanut is approved in a major market; (ii) build an EPIT® pipeline with three ongoing clinical trials; (iii) six months cash runway as defined by the last quarter of spend on the day of severance. Compliance with these performance conditions will be established by our board of directors prior to any payment.

In the event of termination "without cause" or for "good reason", we will pay an amount equal to the sum of: (i) 18 months of Mr. Tassé's base salary and (ii) the target bonus at a 100% achievement level.

In case of termination without "cause" or for "good reason" outside of a change of control, the severance benefits will get paid out over a 12-month period. In case of termination without "cause" or for "good reason" in connection with a change of control, those same amounts get paid in a lump sum.

We have entered into employment agreements with the following executive officers:

*David Schilansky*

In September 2011, we entered into an employment agreement with Mr. Schilansky, our then Chief Operating Officer and Chief Financial Officer and current Deputy Chief Executive Officer, with an effective date as of September 30, 2011. He is entitled to an annual base salary. Mr. Schilansky is also eligible to receive equity grants as our board may determine and to participate in our bonus plan. In addition, in the event of dismissal by us (other than a termination for cause) within 18 months following the appointment of a new Chief Executive Officer, he is entitled to receive an indemnity equivalent to two years of compensation, calculated based on the average of the last 12 months compensation paid (including bonuses and variable compensation), payable in a lump-sum.

*Pascale Ehouarn*

In March 2006, we entered into an employment agreement with Ms. Ehouarn, our then Senior Vice President of Manufacturing & Supply and current Chief Engineering, Manufacturing & Supply Officer. Ms. Ehouarn is entitled to an annual base salary. Ms. Ehouarn is also eligible to receive equity grants as our board may determine and to participate in our bonus plan. In addition, in the event of dismissal by us (other than a termination for cause) within 18 months following the appointment of a new Chief Executive Officer, she is entitled to receive an indemnity equivalent to one year of compensation, calculated based on the average of the last 12 months compensation paid (including bonuses and variable compensation), payable in a lump-sum.

*Susanna Mesa*

In April 2014, we entered into an employment agreement with Ms. Mesa, our then Senior Vice President of Strategy and current Chief Business Officer. Ms. Mesa is entitled to an annual base salary. Ms. Mesa is also eligible to receive equity grants as our board may determine and to participate in our bonus plan.

*Magali Richard*

In October 2016, we entered into an employment agreement with Ms. Richard, our then Senior Vice President of Portfolio Strategy & Business Development and current Chief Strategy Officer. Ms. Richard is entitled to an annual base salary. Ms. Richard is also eligible to receive equity grants as our board may determine and to participate in our bonus plan. In addition, in the event of dismissal by us (other than a termination for cause) within 18 months following the appointment of a new Chief Executive Officer, she is entitled to receive an indemnity equivalent to one year of compensation, calculated based on the average of the last 12 months compensation paid (including bonuses and variable compensation), payable in a lump-sum.

*Sebastien Robitaille*

In September 2015, we entered into an employment agreement with Mr. Robitaille, our then Senior Vice President, Group Controller & Information Systems and current Chief Transformation Officer and Deputy Chief Financial Officer. Mr. Robitaille is entitled to an annual base salary. Mr. Robitaille is also eligible to receive equity grants as our board may determine and to participate in our bonus plan. In addition, in the event of dismissal by us (other than a termination for cause) within 18 months following the appointment of a new Chief Executive Officer, he is entitled to receive an indemnity equivalent to one year of compensation, calculated based on the average of the last 12 months compensation paid (including bonuses and variable compensation), payable in a lump-sum.

*Joan Schmidt*

In June 2018, we entered into an employment agreement with Ms. Schmidt, our Chief Legal Officer. Ms. Schmidt is entitled to an annual base salary. Ms. Schmidt is also eligible to receive equity grants as our board may determine and to participate in our bonus plan.

*Kevin Trapp*

In August 2018, we entered into an employment agreement with Mr. Trapp, our Chief Commercial Officer. Mr. Trapp is entitled to an annual base salary. Mr. Trapp is also eligible to receive equity grants as our board may determine and to participate in our bonus plan.

*Hugh Sampson*

In November 2015, we entered into an employment agreement with Mr. Sampson, our Chief Scientific Officer and current interim Chief Medical Officer. Mr. Sampson is entitled to an annual base salary. Mr. Sampson is also eligible to receive equity grants as our board may determine and to participate in our bonus plan.

*Daniel Soland*

Effective January 2018, we renewed, for a one-year term and with the same conditions, the consulting agreement entered into in January 2017 with our director, Daniel Soland, pursuant to which he has agreed to provide consulting services to us, upon our request from time to time, related to the review of our commercialization strategy. Mr. Soland received a lump sum of €45,000, paid by us on a semi-annual basis.

*Julie O'Neill*

In December 2018, we entered into a consulting agreement with Julie O'Neill, a member of our board of directors, pursuant to which she has agreed to provide chemistry, manufacturing and controls advice. Upon our request, she will: (i) examine and remedy the shortcomings identified by the FDA; (ii) examine and provide answers on all aspects of the technical operations, including, by way of non-exclusive example, process development, analytical development, manufacture, engineering, the procurement chain, quality control and quality assurance and (iii) advise our Chief Executive Officer and our internal services at the request of our Chief Executive Officer. The term of the agreement is for one year. Ms. O'Neill will receive €45,000 per month and will be able eligible to receive certain success fees allocated as follows: (i) a maximum of €200,000 for the resubmision of the BLA to the FDA for for the treatment of peanut allergy in children 4 to 11 of age and; (ii) an additional amount of up to €250,000 if and when the FDA has approved the Viaskin® Peanut BLA. These success fees will, however, be subject to modification at the discretion of our board of directors.

***Director and Executive Officer Compensation***

See "Item 6.B—Compensation of Directors and Executive Officers" for information regarding compensation of directors and executive officers.

***Equity Awards***

Since January 1, 2018, we have issued equity awards to certain of our directors and executive officers:

On January 15, 2018, we issued an aggregate of 8,300 options shares to new U.S. employees.

On April 16, 2018, we issued an aggregate of 16,500 option shares to new U.S. employees.

On May 15, 2018, we issued an aggregate of 16,500 option shares to new U.S. employees.

On June 15, 2018, we issued an aggregate of 23,600 option shares to new U.S. employees.

On June 22, 2018, we issued an aggregate of 50,000 option shares to certain of our executive officers and an aggregate of 486,153 free shares to French employees and French executive officers.

On June 22, 2018, we issued 44,000 non-employee warrants (BSAs) to our directors. Each BSA was issued at a purchase price per BSA of €3.72 and gives the holder the right to subscribe for one ordinary share for a purchase price per share of €37.24.

On July 16, 2018, we issued an aggregate of 28,800 option shares to new U.S. employees.

On August 15, 2018, we issued an aggregate of 33,500 option shares to new U.S. employees.

On September 6, 2018, we issued an aggregate of 65,000 option shares to certain of our executive officers.

On September 17, 2018, we issued an aggregate of 80,900 option shares to new U.S. employees.

On October 15, 2018, we issued an aggregate of 76,700 option shares to new U.S. employees.

On November 1, 2018, we issued an aggregate of 57,000 free shares to new French employees.

On November 15, 2018, we issued an aggregate of 26,000 option shares to new U.S. employees.

On November 29, 2018, we issued an aggregate of 350,000 option shares to our Mr. Tassé. Each stock option gives the holder the right to subscribe for one ordinary share for a purchase price per share of €30.02.

On December 12, 2018, we issued an aggregate of 34,000 option shares to new U.S. employees and an aggregate of 19,950 free shares to new French employees.

On December 15, 2018, we issued an aggregate of 7,200 option shares to new U.S. employees.

See "Item. 7A—Major Shareholders" for information regarding equity awards to our executive officers.

***Bonus Plans***

All our executive officers are entitled to a bonus ranging between 40% and 50% based on yearly objectives determined by our board of directors upon recommendation of our compensation committee.

***Indemnification Agreements***

We intend to enter into indemnification agreements with each of our directors and executive officers. See "Item. 6B—Limitations on Liability and Indemnification Matters."

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**Related-Party Transactions Policy**

We have adopted a related-party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related-party transactions. For purposes of our policy only, a related-party transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related parties are, were or will be participants, which are not (1) in the ordinary course of business, (2) at arms' length and (3) in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. For purposes of this policy, a related party is any executive officer, director (or nominee for director) or beneficial owner of more than five percent (5%) of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related-party transaction, including any transaction that was not a related-party transaction when originally consummated or any transaction that was not initially identified as a related-party transaction prior to consummation, our management must present information regarding the related-party transaction to our board of directors for review, consideration and approval. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third-party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-party transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related-party transactions, our board, or to the extent permitted by applicable law an independent body of our board, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related-party is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally. The policy requires that, in determining whether to approve, ratify or reject a related-party transaction, our board of directors, or if permitted by applicable law an independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our board of directors, or if permitted by applicable law an independent body of our board of directors, determines in the good faith exercise of its discretion.

**C. Interests of Experts and Counsel.**

Not applicable.

## Item 8. Financial Information

**A. Consolidated Statements and Other Financial Information.**

**Consolidated Financial Statements**

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1, and incorporated herein by reference.

**Dividend Distribution Policy**

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business.

Subject to the requirements of French law and our by-laws, dividends may only be distributed from our distributable profits, plus any amounts held in our reserves other than those reserves that are specifically required by law. See "Item 10. B—Memorandum and Articles of Association" for further details on the limitations on our ability to declare and pay dividends. Dividend distributions, if any, will be made in euros and converted into U.S. dollars with respect to the ADSs, as provided in the deposit agreement.

**Legal Proceedings**

On January 15, 2019, Travis Ito-Stone individually and on behalf of all others similarly situated, filed a class action complaint for violation of federal securities laws against us, our former Chief Executive Officer, our current Chief Executive Officer and our Deputy Chief Executive Officer in the United States District Court for the District of New Jersey. The complaint purports to bring a federal securities class action on behalf of a class of persons who acquired our securities between February 14, 2018 and December 19, 2018 and seeks to recover damages caused by defendants' alleged violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 10b-5 promulgated thereunder. The complaint alleges, among other things, that the defendants made materially false and/or misleading statements related to our business, operational and compliance policies. The plaintiff seeks, among other things, the designation of the action as a class action, an award of unspecified compensatory damages, interest, costs and expenses, including counsel fees and expert fees, and other relief as the court deems appropriate.

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

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**B. Significant Changes**

Not applicable.

## Item 9. The Offer and Listing

### A. Offer and Listing Details

The ADS have been listed on Nasdaq Global Select Market under the symbol "DBVT" since October 22, 2014. Prior to that date, there was no public trading market for ADSs. Our ordinary shares have been trading on Euronext Paris under the symbol "DBV" since March 28, 2012. Prior to that date, there was no public trading market for ADSs or our ordinary shares.

### B. Plan of Distribution.

Not applicable.

### C. Markets.

The ADS have been listed on Nasdaq under the symbol "DBVT" since October 22, 2014 and our ordinary shares have been listed on the Euronext Paris under the symbol "DBV" since March 28, 2012.

### D. Selling Shareholders.

Not applicable.

### E. Dilution.

Not applicable.

### F. Expenses of the Issue.

Not applicable.

## Item 10. Additional Information.

### A. Share Capital.

Not applicable.

### B. Memorandum and Articles of Association.

The information set forth in our prospectus dated July 15, 2015, filed with the SEC pursuant to Rule 424(b), under the headings "Description of Share Capital—Key Provisions of Our By-laws and French Law Affecting Our Ordinary Shares," "Description of Share Capital—Differences in Corporate Law" and "Limitations Affecting Shareholders of a French Company" is incorporated herein by reference.

### C. Material Contracts.

***Exclusive Development Collaboration and License Agreement with Nestec S.A. (an affiliate of Nestlé Health Sciences S.A.)***

On May 27, 2016, we entered into a development collaboration and license agreement with Nestec S.A., an affiliate of Nestlé Health Sciences S.A. within the Nestlé group, whom we refer to as Nestlé Health Sciences, for the development and, if approved, commercialization of MAG1C, a ready-to-use and standardized atopy patch test tool for the diagnosis of cow's milk protein allergy, or CMPA, in infants and toddlers.

We entered into an amendment with Nestlé Health Science on July 12, 2018 pursuant to which both parties agreed to adjust the development milestones.

Under the terms of the exclusive collaboration, we are responsible for leading the development activities of MAG1C using our proprietary Viaskin® technology up through a pivotal Phase III clinical program, and if the appropriate regulatory approvals are received, Nestlé Health Sciences has the exclusive license to commercialize MAG1C globally.

We are eligible to receive up to €100.0 million in development, clinical, regulatory and commercial milestones, inclusive of a non-refundable upfront payment of €10.0 million that we received in July 2016. We have agreed to pay for all development-related costs of MAG1C, including the costs of a worldwide clinical program, as well as manufacturing costs. We will also be eligible to receive net-sales-based milestone payments and tiered double-digit royalty payments on global product sales.

The agreement also includes provisions that we may enter into a supply agreement with Nestec under which we would supply Nestlé Health Sciences with MAG1C pursuant to the terms and conditions of a supply agreement to be negotiated in good faith in the future. If we manufacture MAG1C, then Nestlé Health Sciences has agreed to pay us an amount plus a specified mark-up for the supply of MAG1C.

Either party may terminate the agreement if the other party is in material breach and such breach has not been cured within the applicable cure period. The agreement may also be terminated by us for patent challenge and by either party for certain events of insolvency. Upon any termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of MAG1C and certain payment and royalty obligations.

***Underwriting Agreement***

We entered into an underwriting agreement with Morgan Stanley & Co. LLC, Goldman Sachs International, Barclays Capital Inc. and Deutsche Bank Securities Inc., as managers for the underwriters, on March 20, 2018, with respect to the ordinary shares and ADSs sold in our March 2018 underwritten global offering. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribute to payments that the underwriters may be required to make because of such liabilities.

The summaries provided above do not purport to be complete and are qualified in their entirety by reference to the complete agreements, which are attached as exhibits to this Annual Report on Form 20-F. For additional information on our material contracts, please see "Item 4. Information on the Company," "Item 6. Directors, Senior Management and Employees," and "Item 7.B. Related Party Transactions" of this Annual Report on 20-F.

## D. Exchange Controls.

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

## E. Taxation

**Certain Material U.S. Federal Income Tax Considerations**

The following is a summary of certain material U.S. federal income tax considerations relating to the ownership and disposition of ADSs by a U.S. holder (as defined below). This summary addresses only the U.S. federal income tax considerations for U.S. holders of the ADSs that will hold such ADSs as capital assets (generally, property held for investment). This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a "hedging," "integrated" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- partnerships (including entities or arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or persons that will hold the ADSs through such an entity;
- S corporations;
- certain former citizens or long term residents of the United States;
- persons that received ADSs as compensation for the performance of services;
- persons that acquire ADSs as a result of holding or owning our preferred shares;
- holders that own directly, indirectly, or through attribution 10% or more of our ADSs and shares; and
- holders that have a "functional currency" other than the U.S. dollar.

Further, this summary does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the ownership and disposition of the ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the U.S. Internal Revenue Service (the "IRS") will not take a position concerning the tax consequences of the ownership and disposition of the ADSs or that such a position would not be sustained. Holders should consult their own tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of the ADSs in their particular circumstances.

For the purposes of this summary, a "U.S. holder" is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or if such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds ADSs, the U.S. federal income tax consequences relating to an investment in the ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of the ADSs in its particular circumstances.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC.

**Persons considering an investment in the ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the ownership and disposition of the ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.**

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as the beneficial owner of the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares. The U.S. Treasury has expressed concerns that intermediaries in the chain of ownership between the holder of an ADS and the issuer of the security underlying the ADS may be taking actions that are inconsistent with the beneficial ownership by the holder of the underlying security. Accordingly, the creditability of foreign taxes, if any, as described below, could be affected by actions taken by intermediaries in the chain of ownership between the holders of ADSs and our company if as a result of such actions the holders of ADSs are not properly treated as beneficial owners of the underlying ordinary shares.

***Distributions.*** Subject to the discussion under "*Passive Foreign Investment Company Considerations,*" below, the gross amount of any distribution (before reduction for any amounts withheld in respect of French withholding tax) actually or constructively received by a U.S. holder with respect to ADSs will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder's adjusted tax basis in the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. The ADSs are listed on the Nasdaq Global Select Market, which is an established securities market in the United States, and we expect the ADSs to be readily tradable on the Nasdaq Global Select Market. However, there can be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in the current taxable year or later years. The company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital, signed on August 31, 1994, as amended and currently in force, or the U.S.-France Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-France Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under "*Passive Foreign*

*Investment Company Considerations*," below, such dividends will generally be "qualified dividend income" in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any French withholding tax as either a deduction from gross income or a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. holder's U.S. federal income tax liability that such U.S. holder's taxable income bears to such U.S. holder's worldwide taxable income. In applying this limitation, a U.S. holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ADSs that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for French income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. holder receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

***Sale, Exchange or Other Taxable Disposition of the ADSs.*** A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ADSs in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder's tax basis for those ADSs. Subject to the discussion under "*Passive Foreign Investment Company Considerations*" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in the ADSs generally will be equal to the cost of such ADSs.

Capital gain from the sale, exchange or other taxable disposition of ADSs of a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ADSs exceeds one year (i.e., such gain is long-term capital gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder realizes will be U.S. source ordinary income or loss.

***Medicare Tax.*** Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ADSs. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in the ADSs.

***Passive Foreign Investment Company Considerations.*** If we are classified as a passive foreign investment company ("PFIC") in any taxable year, a U.S. holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of its subsidiaries, either: (i) at least 75% of its gross income is "passive income" or (ii) at least 50% of the average quarterly value of its total gross assets (which, if we are publicly traded for the entire year being tested, would be measured by the fair market value of our assets, and for which purpose the total value of our assets may be determined in part by the market value of the ADSs and our ordinary shares, which are subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income."

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of the ADSs. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. holder owns the ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ADSs, regardless of whether we continue to meet the tests described above.

The market value of our assets may be determined in large part by reference to the market price of the ADSs and our ordinary shares, which is likely to fluctuate after the offering. In addition, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from the global offering in our business. Whether we are a PFIC for any taxable year will depend on our assets and income in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year. Nevertheless, based on the composition of our assets and income for our 2018 taxable year, we believe we were not likely a PFIC for our 2018 taxable year and do not expect to be a PFIC for our 2019 taxable year. If we are a PFIC, and you are a U.S. holder, then unless you make one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for the ADSs) and (b) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "Distributions."

Certain elections exist that may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment (such as mark-to-market treatment) of the ADSs. If a U.S. holder makes the mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in the ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and the ADSs are "regularly traded" on a "qualified exchange." The ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). The Nasdaq Global Select Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to a U.S. holder.

We do not currently intend to provide the information necessary for U.S. holders to make qualified electing fund elections if we are treated as a PFIC for any taxable year. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. holder owns ADSs during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the company, generally with the U.S. holder's federal income tax return for that year. If our company were a PFIC for a given taxable year, then you should consult your tax advisor concerning your annual filing requirements.

**The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the ownership and disposition of the ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the ownership and disposition of the ADSs.**

***Backup Withholding and Information Reporting.*** U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of ADSs that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

***Foreign Asset Reporting.*** Certain U.S. holders who are individuals are required to report information relating to an interest in the ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

**THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSS IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.**

**French Tax Consequences**

The following describes the material French tax consequences to U.S. Holders (as defined below) of purchasing, owning and disposing of our ADSs and, unless otherwise noted, this discussion is the opinion of McDermott Will & Emery AARPI, our French tax counsel, insofar as it relates to matters of French tax law and legal conclusions with respect to those matters.

This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of our ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

French tax rules applicable to French assets that are held by or in foreign trusts provide inter alia for the inclusion of trust assets in the settlor's net assets for purpose of assessing the French real estate wealth tax, the French gift and estate tax, the specific tax on value of the French assets, within the scope of the French real estate wealth tax, held in or by foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to ADSs held in trusts. If ADSs are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of securities.

The description of the French income tax and wealth tax consequences set forth below is based on the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, or the Treaty, which came into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax guidelines issued by the French tax authorities in force as of the date of this Annual Report on Form 20-F (the "Treaty").

For the purposes of this discussion, a "U.S. Holder" is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes: (1) an individual who is a citizen or resident of the United States; (2) a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia; (3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or (4) a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity treated as partnership for U.S. federal income tax purposes) holds ADSs, the tax treatment of the partnership and a partner in such partnership generally will depend on the status of the partner and the activities of the partnership. Such partner or partnership is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of securities.

This discussion applies only to investors that hold ADSs as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the ''Limitation on Benefits'' provision contained in the Treaty, and whose ownership of the ADSs is not effectively connected to a permanent establishment or a fixed base in France. Certain U.S. Holders (including, but not limited to,

U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the securities pursuant to the exercise of employee share options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes and persons holding securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below.

U.S. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of securities in light of their particular circumstances, especially with regard to the ‘‘Limitations on Benefits’’ provision.

**Estate and Gift Taxes and Transfer Taxes**

In general, a transfer of securities by gift or by reason of death of a U.S. Holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978 (as amended by the protocol of December 8, 2014), unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the *Code général des impôts* (French Tax Code, or FTC), purchases of shares or ADSs of a French company listed on a regulated market of the European Union or an exchange formally acknowledged by the French Financial Market Authority (AMF) are subject to a 0.3% French tax on financial transactions provided that the issuer’s market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of French relevant companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year is published annually by the French State. Although we were included in the list published for calendar years 2016 and 2017, we were not included in the list published for calendar year 2018 and 2019 but this may change in the future.

Pursuant to Article 726 II d) of the FTC, transfers of securities that are subject to the French tax on financial transactions are exempt from any transfer tax in France. Conversely, in the case where Article 235 ter ZD of the FTC is not applicable, transfers of shares issued by a French listed company may be subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written statement (“*acte*”) executed either in France or outside France.

**Wealth Tax**

The French real estate wealth tax (*impôt sur la fortune immobilière*), introduced by French Finance Bill dated December 30th 2017, applies only to individuals who own, directly or indirectly through one or more legal entities, real estate property in France (subject to certain exemptions) and whose net taxable assets amount to at least €1,300,000.

French real estate wealth tax may only apply to U.S. Holders, with respect to shares, rights or interest in a company, to the extent such company holds real estate assets that are not allocated to its operational activity, for the fraction of the value of shares, rights or interest in the company representing such real estate assets. In any case, pursuant to Article 965 2° of the FTC, shares of an operating entity holding French real estate assets in which the taxpayer holds, directly and indirectly, less than 10% of the share capital or voting rights are exempt from real estate wealth tax.

**Taxation of Dividends**

Dividends paid by a French corporation to non-residents of France are generally subject to French withholding tax at a rate of 12.8% when the recipient is an individual and 30% otherwise. Dividends paid by a French corporation in a non-cooperative State or territory, as defined in Article 238-0 A of the FTC, will generally be subject to French withholding tax at a rate of 75%.

However, eligible U.S. Holders, other than individuals subject to the French withholding tax at a rate of 12.8%, entitled to Treaty benefits under the ‘‘Limitation on Benefits’’ provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. Holder which is a U.S. resident as defined pursuant to the provisions of the Treaty and which ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. Holder has in France may be capped at 15%, or 5% if such U.S. Holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuer; such U.S. Holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any.

For U.S. Holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates, contained in the ‘‘Limitation on Benefits’’ provision of the Treaty, are complex. U.S. Holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. Holder may immediately be subject to the reduced rates provided that such U.S. Holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a U.S. Holder, other than individuals subject to the French withholding tax at a rate of 12.8%, that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 30%, or 75% if paid in a non-cooperative State or territory (as defined in Article 238-0 A of the FTC), and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the depositary with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Certain qualifying pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. Holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. Holders registered with the depositary. The depositary will arrange for the filing with the French Tax authorities of all such forms properly completed and executed by U.S. Holders of ordinary shares or ADSs and returned to the depositary in sufficient time so that they may be filed with the French tax authorities before the distribution in order to obtain immediately a reduced withholding tax rate.

The withholding tax refund, if any, ordinarily occurs within 12 months from filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend was paid.

Since the withholding tax rate applicable under French domestic law to U.S. Holders who are individuals does not exceed the cap provided in the Treaty (i.e. 15%), the 12.8% rate shall apply, without any reduction provided under the Treaty.

**Tax on Sale or Other Disposition**

In general, under the Treaty, a U.S. Holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption, sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. Holder has in France. Special rules apply to U.S. Holders who are residents of more than one country.

### F. Dividends and Paying Agents.

Not applicable.

### G. Statement by Experts.

Not applicable.

### H. Documents on Display.

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.dbv-technologies.com*. We intend to post our Annual Report on Form 20-F on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as DBV Technologies, that file electronically with the SEC.

With respect to references made in this Annual Report on Form 20-F to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report on Form 20-F for copies of the actual contract or document.

### I. Subsidiary Information

Not required.

## Item 11. Quantitative and Qualitative Disclosures About Market Risk.

***Interest Rate Risk***

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

***Foreign Currency Exchange Risk***

We are exposed to foreign exchange risk inherent in some of our supplies obtained in the United States, which have been invoiced in U.S. dollars. As of this date, we do not have revenues in dollars nor in any other currency other than the euro. Due to the relatively low level of these expenditures we believe our exposure to foreign exchange risk is unlikely to have a material adverse impact on our results of operations or financial position. Our exposure to currencies other than the U.S. dollar is negligible.

For 2018, approximately 34% of our purchases and other external expenses have been made in U.S. dollars compared with less than 12% in 2017 and 2016. Exchange rate effects have a non-significant impact on the Group's consolidated net position. At this stage, the company has not put in place any hedging instruments.

***Liquidity Risk***

As of December 31, 2018, we had €122.8 million in cash and cash equivalents compared to €137.9 million of cash and cash equivalents as of December 31, 2017. We have incurred operating losses and negative cash flows from operations since inception, incurred a net loss of €166.1 million during the year ended December 31, 2018, and have an accumulated deficit and reserves of €254.9 million as of December 31, 2018. Net cash used in operating activities was €136.6 million for the year ended December 31, 2018 and €114.3 million for the year ended December 31, 2017.

We have primarily funded these losses through equity financings, and by obtaining public assistance in support of innovation and reimbursements of research tax credit. To date, we have not generated any product revenue and we continue to prepare for the potential launch of our Viaskin® Peanut product candidate in North America planned in 2020 for which its BLA submission to the US FDA is expected in the third quarter of 2019. We expect operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support our operating plan for the next 12 months despite additional funds raised in March 2018. We expect to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding our ability to continue as a going concern.

We expect to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

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

***Inflation Risk***

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

## Item 12. Description of Securities Other than Equity Securities.

### A. Debt Securities.

Not applicable.

### B. Warrants and Rights.

Not applicable.

### C. Other Securities.

Not applicable.

### D. American Depositary Shares.

Citibank, N.A., as depositary, registers and delivers American Depositary Shares, also referred to as ADSs. Each ADS represents one-half of one ordinary share (or a right to receive one-half of one ordinary share) deposited with Citibank International Plc, located at EGSP 186, 1 North Wall Quay, Dublin 1 Ireland or any successor, as custodian for the depositary. Each ADS will also represent any other securities, cash or other property which may be held by the depositary in respect of the depositary facility. The depositary's corporate trust office at which the ADSs will be administered is located at 388 Greenwich Street, New York, New York 10013.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report on Form 20-F.

**Fees and Charges**

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

| *Service* | *Fees* |
|---|---|
| • Issuance of ADSs | Up to U.S. $0.05 per ADS issued |
| • Cancellation of ADSs | Up to U.S. $0.05 per ADS canceled |
| • Distribution of cash dividends or other cash distributions | Up to U.S. $0.05 per ADS held |
| • Distribution of ADSs pursuant to stock dividends, free stock distributions or exercise of rights. | Up to U.S. $0.05 per ADS held |
| • Distribution of securities other than ADSs or rights to purchase additional ADSs | Up to U.S. $0.05 per ADS held |
| • ADS Services | Up to U.S. $0.05 per ADS held on the applicable record date(s) established by the depositary |

The holders of ADSs will also be responsible to pay certain fees and expenses incurred by the depositary and certain taxes and governmental charges such as:

- fees for the transfer and registration of ordinary shares charged by the registrar and transfer agent for the ordinary shares in France (i.e., upon deposit and withdrawal of ordinary shares);
- expenses incurred for converting foreign currency into U.S. dollars;
- expenses for cable, telex and fax transmissions and for delivery of securities;
- taxes and duties upon the transfer of securities (i.e., when ordinary shares are deposited or withdrawn from deposit); and
- fees and expenses incurred in connection with the delivery or servicing of ordinary shares on deposit.

Depositary fees payable upon the issuance and cancellation of ADSs are typically paid to the depositary by the brokers (on behalf of their clients) receiving the newly issued ADSs from the depositary and by the brokers (on behalf of their clients) delivering the ADSs to the depositary for cancellation. The brokers in turn charge these fees to their clients. Depositary fees payable in connection with distributions of cash or securities to ADS holders and the depositary services fee are charged by the depositary to the holders of record of ADSs as of the applicable ADS record date.

The depositary fees payable for cash distributions are generally deducted from the cash being distributed. In the case of distributions other than cash (*i.e.*, stock dividend, rights), the depositary charges the applicable fee to the ADS record date holders concurrent with the distribution. In the case of ADSs registered in the name of the investor (whether certificated or uncertificated in direct registration), the depositary sends invoices to the applicable record date ADS holders. In the case of ADSs held in brokerage and custodian accounts (via DTC), the depositary generally collects its fees through the systems provided by DTC (whose nominee is the registered holder of the ADSs held in DTC) from the brokers and custodians holding ADSs in their DTC accounts. The brokers and custodians who hold their clients' ADSs in DTC accounts in turn charge their clients' accounts the amount of the fees paid to the depositary.

In the event of refusal to pay the depositary fees, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees from any distribution to be made to the ADS holder.

Note that the fees and charges the holders of ADSs may be required to pay may vary over time and may be changed by us and by the depositary. The holders of ADSs will receive prior notice of such changes.

The depositary may reimburse us for certain expenses incurred by us in respect of the ADR program established pursuant to the deposit agreement, by making available a portion of the depositary fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary may agree from time to time.

## PART II

### Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

### Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

Not applicable.

### Item 15. Controls and Procedures

**Disclosure Controls and Procedures**

We maintain "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer (*principal executive officer*) and chief operating officer (*principal financial officer*), as appropriate, to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of December 31, 2018, have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level, having implemented the remediation actions described further below.

***Management's Annual Report on Internal Control over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Under the supervision and with the participation of our chief executive officer (*principal executive officer*) and deputy chief executive officer (*principal financial officer*), management assessed our internal control over financial reporting based upon the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

***Attestation Report of the Registered Public Accounting Firm***

Our independent registered public accounting firm, Deloitte & Associés, has audited the consolidated financial statements included in this Annual Report on Form 20-F, and as part of its audit, has issued its report on the effectiveness of our internal control over financial reporting. This report is included on page F-3 of this Form 20-F and is incorporated herein by reference.

### Item 16. Reserved.

Not applicable.

**Item 16A. Audit Committees Financial Expert.**

Our board of directors has determined that Claire Giraut is an audit committee financial expert as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Claire Giraut is independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.

**Item 16B. Code of Business Conduct and Ethics.**

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, executive officers and directors. A copy of the Code of Conduct is available on our website at *www.dbv-technologies.com*.

**Item 16C. Principal Accountant Fees and Services.**

Deloitte & Associés, or Deloitte, has served as our independent registered public accounting firm for 2017 and 2018. Our accountants billed the following fees to us for professional services in each of those fiscal years:

| | Year Ended December 31, | |
|---|---|---|
| | 2017 | 2018 |
| | (thousands of Euros) | |
| Audit Fees | € 628 | € 696 |
| Audit-Related Fees | — | — |
| Tax Fees | — | — |
| Other Fees | 9 | — |
| Total | € 637 | € 696 |

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that Deloitte provides, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

"Tax Fees" are the aggregate fees billed for professional services rendered by Deloitte for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by Deloitte.

There were no "Audit Related Fees" or "Tax Fees" or billed or paid during 2017 or 2018.

**Audit and Non-Audit Services Pre-Approval Policy**

The audit committee has responsibility for appointing, setting compensation of and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the audit committee has adopted a policy governing the pre-approval of all audit and permitted non-audit services performed by our independent registered public accounting firm to ensure that the provision of such services does not impair the independent registered public accounting firm's independence from us and our management. Unless a type of service to be provided by our independent registered public accounting firm has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Pursuant to its pre-approval policy, the audit committee may delegate its authority to pre-approve services to the chairperson of the audit committee. The decisions of the chairperson to grant pre-approvals must be presented to the full audit committee at its next scheduled meeting. The audit committee may not delegate its responsibilities to pre-approve services to the management.

The audit committee has considered the non-audit services provided by Deloitte as described above and believes that they are compatible with maintaining Deloitte's independence as our independent registered public accounting firm.

**Item 16D. Exemptions from the Listing Standards for Audit Committees.**

Not applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.**

Not applicable.

**Item 16F. Change in Registrant's Certifying Accountant.**

Not applicable.

**Item 16G. Corporate Governance.**

As a French *société anonyme*, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Global Select Market, we are subject to Nasdaq corporate governance standards. However, Nasdaq listing rules provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq rules, with certain exceptions. Currently, we comply with the corporate governance listing standards to the extent possible under French law.

We currently rely on certain exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq corporate governance requirements that would otherwise require us to (1) have a majority of the board of directors consist of independent directors; (2) establish a nominating and corporate governance committee; (3) maintain a compensation committee composed entirely of independent directors; and (4) hold separate executive sessions at which only independent directors are present.

The following are the significant ways in which our corporate governance practices differ from those required for U.S. companies listed on Nasdaq:

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act relating to audit committee composition and responsibilities. Rule 10A-3 provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our general shareholders' meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least 33 $^{1}/_{3}$% of the outstanding shares of the company's common voting stock. Consistent with French law, our by-laws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months.

**Item 16H. Mine Safety Disclosure.**

Not applicable.

## PART III

**Item 17. Financial Statements.**

See pages F-1 through F-76 of this Annual Report on Form 20-F.

**Item 18. Financial Statements.**

Not applicable.

**Item 19. Exhibits.**

## EXHIBIT INDEX

| Exhibit | Description | Incorporated by Reference | | | |
|---|---|---|---|---|---|
| | | Schedule/ Form | File Number | Exhibit | File Date |
| 1.1 | By-laws (*statuts*) of the registrant (English translation) | Form 20-F | 001-36697 | 1.1 | 03/16/18 |
| 2.1 | Form of Deposit Agreement | Form F-1/A | 333-198870 | 4.1 | 10/15/14 |
| 2.2 | Form of American Depositary Receipt | Form F-1/A | 333-198870 | 4.1 | 10/15/14 |
| 4.1 | Office Lease between the registrant and GENERALI VIE, dated March 3, 2015 (English translation) | Form 20-F | 001-36697 | 4.2 | 04/29/15 |
| 4.2 | Commercial Lease between the registrant and SELECTINVEST 1, dated April 28, 2011 (English translation) | Form F-1 | 333-198870 | 10.1 | 09/22/14 |
| 4.3 | Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hopitaux de Paris and Université Paris Descartes, dated January 7, 2009 (English translation) | Form F-1 | 333-198870 | 10.2 | 09/22/14 |
| 4.4# | Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated May 27, 2016 | Form 20-F | 001-36697 | 4.14 | 03/22/17 |
| 4.5+* | Amendment to Development Collaboration and License Agreement between the registrant and NESTEC S.A., dated July 12, 2018 | | | | |
| 4.6† | Form of Indemnification Agreement between the registrant and each of its executive officers and directors | Form F-1/A | 333-198870 | 10.3 | 10/15/14 |
| 4.7† | 2013 and 2014 Share Option Plans (English translation) | Form F-1 | 333-198870 | 10.4 | 09/22/14 |
| 4.8† | 2012, 2013 and 2014 Free Share Plans (English translation) | Form F-1 | 333-198870 | 10.5 | 09/22/14 |
| 4.9† | Summary of BSA | Form F-1 | 333-198870 | 10.6 | 09/22/14 |
| 4.10† | Summary of BSPCE | Form F-1 | 333-198870 | 10.7 | 09/22/14 |
| 4.11† | 2015 Share Option Plan (English translation) | Form 20-F | 001-36697 | 4.10 | 04/28/16 |
| 4.12† | 2015 Free Share Plans (English translation) | Form 20-F | 001-36697 | 4.11 | 04/28/16 |
| 4.13† | 2016 Share Option Plan (English translation) | Form 20-F | 001-36697 | 4.12 | 03/22/17 |
| 4.14† | 2016 Free Share Plan (English translation) | Form 20-F | 001-36697 | 4.13 | 03/22/17 |

| | | | | | |
|---|---|---|---|---|---|
| 4.15† | 2017 Share Option Plan (English translation) | Form 20-F | 001-36697 | 4.14 | 03/16/18 |
| 4.16† | 2017 Free Share Plan (English translation) | Form 20-F | 001-36697 | 4.15 | 03/16/18 |
| 4.17†* | 2018 Share Option Plan (English translation) | | | | |
| 4.18†* | 2018 Free Share Plan (English translation) | | | | |
| 4.19 | Underwriting Agreement, dated as of March 20, 2018, among the registrant and Morgan Stanley & Co. LLC, Goldman Sachs International, Barclays Capital Inc. and Deutsche Bank Securities Inc., as managers for the several underwriters named therein. | Form 6-K | 001-36697 | 1.1 | 03/21/18 |
| 4.20 | Registration Rights Agreement, dated as of March 23, 2018, between the registrant, 667, L.P. and Baker Brothers Life Sciences, L.P. | Form 6-K | 001-36697 | 4.1 | 03/23/18 |
| 8.1* | List of subsidiaries of the registrant | | | | |
| 12.1* | Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | |
| 12.2* | Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | |
| 13.1** | Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 13.2** | Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | |
| 15.1* | Consent of Deloitte & Associés | | | | |
| 101.INS* | XBRL Instance Document | | | | |
| 101.SCH* | XBRL Taxonomy Extension Schema Document | | | | |
| 101.CAL* | XBRL Taxonomy Extension Calculation Linkbase Document | | | | |
| 101.DEF* | XBRL Taxonomy Extension Definition Linkbase Document | | | | |
| 101.LAB* | XBRL Taxonomy Extension Label Linkbase Document | | | | |
| 101.PRE* | XBRL Taxonomy Extension Presentation Linkbase Document | | | | |

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or any compensatory plan, contract or arrangement.
# Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.
+ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been submitted separately with the Securities and Exchange Commission.

## Index to Financial Statements

## Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of DBV Technologies SA

### Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of DBV Technologies S.A. and subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of (loss), comprehensive (loss), cash flows and shareholders' equity, for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated April 1, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

### Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred operating losses and negative cash flows from operations since inception and current cash and cash equivalents on hand are not projected to be sufficient to support the Company's current operating plan. These matters raise substantial doubt about the ability of the Company to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Associés

Paris-La Défense, France
April 1, 2019

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

**Report of Independent Registered Public Accounting Firm**
**Internal Control Over Financial Reporting**

To the Shareholders and Board of Directors of DBV Technologies SA

**Opinion on Internal Control over Financial Reporting**

We have audited the internal control over financial reporting of DBV Technologies S.A. and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2018 of the Company and our report dated April 1, 2019, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's ability to continue as a going concern.

**Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Associés

Paris-La Défense, France
April 1, 2019

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**
**(Amounts in thousands of Euros)**

| | Note | Year Ended December 31, 2016 | 2017 | 2018 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-Current assets** | | | | |
| Intangible assets | **4** | 96 | 123 | 29 |
| Property, plant, and equipment | **5** | 12,482 | 17,808 | 20,219 |
| Other non-current financial assets | **6** | 2,745 | 3,012 | 6,033 |
| **Total non-current assets** | | **15,323** | **20,942** | **26,281** |
| **Current assets** | | | | |
| Inventories | **7** | — | — | 1,566 |
| Customer accounts receivable and related receivables | **8** | 1,250 | 1,265 | — |
| Other current assets | **8** | 14,454 | 17,721 | 21,131 |
| Cash and cash equivalents | **9** | 256,473 | 137,880 | 122,770 |
| **Total current assets** | | **272,177** | **156,865** | **145,468** |
| **TOTAL ASSETS** | | **287,500** | **177,807** | **171,749** |

| | Note | Year Ended December 31, 2016 | 2017 | 2018 |
|---|---|---|---|---|
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | | | |
| **Shareholders' equity** | | | | |
| Share Capital | **10** | 2,465 | 2,499 | 3,016 |
| Premiums related to the Share Capital | | 405,882 | 406,709 | 539,292 |
| Reserves | | (50,968) | (131,592) | (254,946) |
| Net (loss) | | (114,531) | (147,693) | (166,076) |
| **Total shareholders' equity** | | **242,849** | **129,923** | **121,286** |
| **Non-current liabilities** | | | | |
| Long-term financial debt | **11** | 4,049 | 1,825 | 1,278 |
| Non-current provisions | **12** | 853 | 1,260 | 1,536 |
| Other non-current liabilities | **11** | 10,746 | 8,869 | 4,105 |
| **Total non-current liabilities** | | **15,649** | **11,954** | **6,919** |
| **Current liabilities** | | | | |
| Bank overdrafts | | — | — | — |
| Short-term financial debt | **11** | 591 | 2,325 | 1,201 |
| Current provisions | | — | 913 | 1,270 |
| Supplier accounts payable | **13** | 13,720 | 16,941 | 28,567 |
| Other current liabilities | **13** | 14,692 | 15,751 | 12,506 |
| **Total current liabilities** | | **29,002** | **35,930** | **43,543** |
| **TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY** | | **287,500** | **177,807** | **171,749** |

*The accompanying notes form an integral part of these consolidated financial statements.*

**CONSOLIDATED STATEMENTS OF (LOSS)**
**(Amounts in thousands of Euros except share and per share data)**

| | Note | Year Ended December 31, 2016 | 2017 | 2018 |
|---|---|---|---|---|
| **Operating income** | | | | |
| Revenues | **15** | — | — | — |
| Other income | **15** | 9,084 | 11,909 | 14,537 |
| **Total income** | | **9,084** | **11,909** | **14,537** |
| **Operating expenses** | | | | |
| Cost of goods sold | | — | — | — |
| Research & Development | **16/17** | (78,828) | (105,232) | (107,171) |
| Sales & Marketing | **16/17** | (11,282) | (15,824) | (32,169) |
| General & Administrative | **16/17** | (35,005) | (35,837) | (41,399) |
| **Total expenses** | | **(125,115)** | **(156,892)** | **(180,739)** |
| **Operating (loss)** | | **(116,031)** | **(144,983)** | **(166,202)** |
| Financial revenues | **18** | 1,516 | 616 | 493 |
| Financial expenses | **18** | (16) | (3,325) | (351) |
| **Financial profit (loss)** | | **1,500** | **(2,709)** | **141** |
| Income tax | **19** | (0) | (1) | (15) |
| **Net (loss)** | | **(114,531)** | **(147,693)** | **(166,076)** |
| **Basic/diluted (loss) per share (€/share)** | **22** | **(4.68)** | **(5.97)** | **(5.74)** |

*The accompanying notes form an integral part of these consolidated financial statements.*

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS)**
**(Amounts in thousands of Euros)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| **Net (loss)** | **(114,531)** | **(147,693)** | **(166,076)** |
| Actuarial gains and losses on employee benefits, net of corporate tax | (249) | (177) | 19 |
| **Profit (loss) directly recognized in shareholders' equity** | **(249)** | **(177)** | **19** |
| Other comprehensive income | (743) | 3,280 | (683) |
| **Total comprehensive (loss)** | **(115,523)** | **(144,590)** | **(166,740)** |

In accordance with IAS 1 *Presentation of Financial Statements*, the Group, as defined in Note 2, presents a combined statement of other elements of comprehensive (loss).

*The accompanying notes form an integral part of these consolidated financial statements.*

**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(Amounts in thousands of Euros)**

| | Note | 2016 | 2017 | 2018 |
|---|---|---|---|---|
| | | K€ | K€ | K€ |
| **Net (loss) for the period** | | **(114,531)** | **(147,693)** | **(166,076)** |
| ***Reconciliation of the net (loss) and the cash used for the operating activities:*** | | | | |
| **Cash flows used in operating activities:** | | | | |
| Amortization and provision | | 1,349 | 2,926 | 2,830 |
| Retirement pension obligations | | 115 | 230 | 295 |
| Expenses related to share-based payments | | 34,353 | 30,781 | 25,904 |
| Other elements | | 147 | 130 | 752 |
| **Operating cash flows before change in working capital** | | **(78,566)** | **(113,626)** | **(136,294)** |
| Inventories | | — | — | (1,566) |
| Customer accounts receivable | | (1,250) | 3 | 1,229 |
| Other current assets | | (2,931) | (3,458) | (2,591) |
| Supplier accounts payable | | 3,645 | 3,333 | 9,095 |
| Other current and non-current liabilities | | 19,564 | (566) | (6,493) |
| **Change in working capital requirement** | | **19,028** | **(687)** | **(326)** |
| **Net cash flow used in operating activities** | | **(59,538)** | **(114,314)** | **(136,620)** |
| **Cash flows used in investing activities:** | | | | |
| Acquisitions of property, plant, and equipment | **5** | (7,992) | (7,246) | (4,710) |
| Acquisitions of intangible assets | **4** | (215) | (299) | (41) |
| Acquisitions of non-current financial assets | | (93) | (289) | (3,890) |
| **Net cash flows used in investing activities** | | **(8,300)** | **(7,834)** | **(8,641)** |
| **Cash flows provided by financing activities:** | | | | |
| (Decrease) in conditional advances | **11** | (275) | (578) | (1,800) |
| Treasury shares | | (54) | (25) | (479) |
| Capital increases, net of transaction costs | **10** | 2,016 | 861 | 133,099 |
| Other cash flows related to financing activities | | (21) | 28 | (144) |
| **Net cash flows provided by financing activities** | | **1,666** | **286** | **130,676** |
| **(Decrease) in cash** | | **(66,172)** | **(121,863)** | **(14,586)** |
| Net Cash and cash equivalents at the beginning of the period | | 323,381 | 256,473 | 137,880 |
| Impact of exchange rate fluctuations | | (735) | 3,269 | (525) |
| **Net cash and cash equivalents at the close of the period** | **9** | **256,473** | **137,880** | **122,770** |

*The accompanying notes form an integral part of these consolidated financial statements.*

**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**
**(Amounts in thousands of Euros except for the number of shares)**

| | Share capital Shares of Common Stock | | | | | |
|---|---|---|---|---|---|---|
| | Number of Shares | Amount | Premiums related to the Share Capital | Reserve | Profit (loss) | Total Share-holders' Equity |
| **At January 1, 2016** | **24,205,129** | **2,421** | **403,910** | **(39,580)** | **(44,674)** | **322,076** |
| Net (loss) | — | — | — | — | (114,531) | (114,531) |
| Foreign exchange translation | — | — | — | (743) | — | (743) |
| Profit directly recognized in shareholders' equity | — | — | — | (249) | — | (249) |
| **Total (loss) directly recognized in shareholders' equity** | | | | **(992)** | **(114,531)** | **(115,523)** |
| Allocation of prior (loss) | — | — | — | (44,674) | 44,674 | — |
| Increase in capital | 443,699 | 44 | 1,395 | — | — | 1,439 |
| Treasury shares | — | — | — | (74) | — | (74) |
| Issue of share warrants | — | — | 577 | — | — | 577 |
| Share-based payments | — | — | — | 34,353 | — | 34,353 |
| **At December 31, 2016** | **24,648,828** | **2,465** | **405,882** | **(50,968)** | **(114,531)** | **242,849** |
| Net (loss) | — | — | — | — | (147,693) | (147,693) |
| Foreign exchange translation | — | — | — | 3,280 | — | 3,280 |
| (Loss) directly recognized in shareholders' equity | — | — | — | (177) | — | (177) |
| **Total (loss) directly recognized in shareholders' equity** | **—** | **—** | **—** | **3,103** | **(147,693)** | **(144,590)** |
| Allocation of prior (loss) | — | — | — | (114,531) | 114,531 | — |
| Increase in capital | 341,994 | 34 | 536 | — | — | 571 |
| Treasury shares | — | — | — | 23 | — | 23 |
| Issue of share warrants | — | — | 290 | — | — | 290 |
| Share-based payments | — | — | — | 30,781 | — | 30,781 |
| **At December 31, 2017** | **24,990,822** | **2,499** | **406,709** | **(131,592)** | **(147,693)** | **129,923** |
| Net (loss) | — | — | — | — | (166,076) | (166,076) |
| Foreign exchange translation | — | — | — | (683) | — | (683) |
| (Loss) directly recognized in shareholders' equity | — | — | — | 19 | — | 19 |
| **Total (loss) directly recognized in shareholders' equity** | **—** | **—** | **—** | **(665)** | **(166,076)** | **(166,740)** |
| Allocation of prior (loss) | — | — | — | (147,693) | 147,693 | — |
| Increase in capital | 5,166,955 | 517 | 132,419 | — | — | 132,936 |
| Treasury shares | — | — | — | (900) | — | (900) |
| Issue of share warrants | — | — | 164 | — | — | 164 |
| Share-based payments | — | — | — | 25,904 | — | 25,904 |
| **At December 31, 2018** | **30,157,777** | **3,016** | **539,292** | **(254,946)** | **(166,076)** | **121,286** |

*The accompanying notes form an integral part of these consolidated financial statements.*

## NOTES TO THE FINANCIAL STATEMENTS

### Note 1: The Company

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

*Viaskin® Peanut*

The Company's lead product candidate, Viaskin® Peanut, has completed a global Phase III program for the treatment of peanut-allergic patients 4 to 11 years of age. In October 2018, the Company announced its submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age. On December 19, 2018, the Company announced that, after discussions with the U.S. FDA, the Company voluntarily withdrew its Biologics License Application ("BLA") for Viaskin® Peanut in children 4 to 11 years of age.. On February 13, 2019, the Company announced that it expects to resubmit its BLA to the FDA for Viaskin® Peanut for the treatment of peanut-allergic children 4 to 11 years of age in the third quarter of 2019.

In August 2017, the Company initiated Part A of the EPITOPE (EPIT® in Toddlers with Peanut Allergy) trial, a Phase III trial of Viaskin® Peanut in peanut-allergic toddlers ages one to three. EPITOPE is a two-part, pivotal Phase III clinical trial assessing the safety and efficacy of Viaskin® Peanut 250 µg for the treatment of peanut-allergic toddlers one to three years of age. In September 2018, the Company announced that the independent data safety and monitoring board ("DSMB") completed its review of Part A of EPITOPE and recommended that the dose of Viaskin® Peanut 250 µg be evaluated in Part B. On October 26, 2018, the Company announced that the first patient was enrolled in Part B of EPITOPE. This trial is the second Phase III clinical program currently investigating the use of Viaskin® Peanut for the treatment of patients with peanut allergy.

*Viaskin® Milk*

The Company is developing its second product candidate, Viaskin® Milk, for the treatment of cow's milk protein allergy, or CMPA, in children two to 17 years of age, which received fast track designation from the FDA in September 2016. In November 2014, the Company initiated a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin® Milk in 198 patients with Immunoglobulin E, or IgE, mediated CMPA, which the Company refers to as the Milk Efficacy and Safety, or MILES, trial. In June 2015, we announced completion of Part A of the MILES study, or Phase I, and we launched Part B, or Phase II, in October 2015. In February 2018, the Company announced preliminary results from Part B of the MILES study. Following analyses of the data, the 300 µg dose was identified as the dose with the greatest observed clinical activity for children (intent-to-treat, p=0.042). The Company believes these preliminary results support further advancement of the Viaskin® Milk program and intends to discuss findings with regulatory authorities to determine the design of future studies. All patients in the open-label extension trial are being switched to the 300 µg dose for treatment of up to 24 months.

*Viaskin® Egg*

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

*Other Viaskin® application*

In addition to our development programs in food allergies, we are exploring the use of our Viaskin® technology for the treatment of inflammatory and autoimmune diseases with high unmet medical need. Human proof-of-concept trials are ongoing with Viaskin® in Eosinophilic Esophagitis (EoE) and as a booster vaccination against Bordetella pertussis (whooping cough) in healthy adults. The Company's other earlier stage research programs include vaccination for respiratory syncytial virus, as well as potential treatments for celiac disease and type I diabetes.

**Main events in 2018**

1. FINANCING

On March 23, 2018, the Company announced the closing of an underwritten global offering of an aggregate of 3,527,752 ordinary shares in (i) a public offering of 1,392,015 ordinary shares in the form of 2,784,030 American Depositary Shares ("ADSs") in the United States, Canada and certain other countries outside Europe at a public offering price of $21.26 per ADS (on the basis of an exchange rate of $1.2246=€1.00) and (ii) a concurrent private placement of 2,135,737 ordinary shares in Europe (including France) at a public offering price of €34.71 per ordinary share. Each ADS represents the right to receive one-half of one ordinary share.

In addition, on March 26, 2018, the Company announced the issuance and the settlement and delivery of an aggregate of an additional 529,162 ordinary shares, including 208,802 ordinary shares in the form of 417,604 ADSs, on the same terms and conditions as the securities previously sold in the global offering, pursuant to the exercise of the underwriters' option to purchase additional ordinary shares, including in the form of ADSs, in the Company's previously announced global offering (the "Option Closing"). Following the Option Closing, the gross proceeds to the Company from the global offering were approximately $172.5 million (approximately €140.8 million), before deducting underwriting commissions and estimated offering expenses.

2. CLINICAL PROGRAMS

*Viaskin® Peanut*

On February 14, 2018, the Company provided an update on the regulatory progress for Viaskin® Peanut and announced that the U.S. Food and Drug Administration (FDA) has agreed that the available efficacy and safety data for Viaskin® Peanut supports the submission of a Biologics License Application (BLA) for the treatment of peanut allergy in children 4 to 11 years of age.

The FDA provided written responses to the clinical pre-BLA meeting package submitted by the Company, which reflected agreement on the content of the clinical module of the BLA for Viaskin® Peanut.

On October 22, 2018, the Company announced the submission of a BLA to the FDA for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age. On December 19, 2018, the Company announced it voluntarily withdrew its BLA for Viaskin® Peanut following correspondence with the FDA regarding additional data requirements on manufacturing procedures and quality controls.

On December 19, 2018, the Company announced that, after discussions with the FDA, the Company voluntarily withdrew its BLA for Viaskin® Peanut in children 4 to 11 years of age. On February 13, 2019, the Company announced that it expects to resubmit its BLA to the FDA for Viaskin® Peanut for the treatment of peanut-allergic children 4 to 11 years of age in the third quarter of 2019.

On September 12, 2018, the Company announced that the independent DSMB completed its planned safety review of Part A of the EPITOPE (EPIT® in TOddlers with PEanut Allergy) trial of Viaskin® Peanut in peanut-allergic toddlers ages one to three. The Company announced on October 26, 2018 that the first patient was enrolled in Part B of the EPITOPE (EPIT® in Toddlers with Peanut Allergy) trial. EPITOPE is a two-part, pivotal Phase III clinical trial assessing the safety and efficacy of Viaskin® Peanut 250 µg for the treatment of peanut-allergic toddlers one to three years of age. This trial is the second Phase III clinical program currently investigating the use of Viaskin® Peanut for the treatment of patients with peanut allergy.

*Viaskin® Milk*

On February 26, 2018, the Company announced preliminary results from Part B, or Phase II, of a Phase I/II study evaluating the efficacy and safety of three dose regimens of Viaskin® Milk (150 µg, 300 µg, 500 µg) in 198 patients for the treatment of IgE-mediated cow's milk protein allergy (CMPA). The MILES (Milk Efficacy and Safety) study was designed to determine a safe and effective dose in two age groups: children aged two to 11 and adolescents aged 12 to 17. Following analyses of the data, the 300 µg dose was identified as the most effective tested dose for children (intent-to-treat (ITT), p=0.042). The Company believes these preliminary results support further advancement of the Viaskin® Milk program and intends to discuss findings with health authorities in key markets worldwide to determine the design of future studies.

3. CHANGE IN THE GROUP'S EXECUTIVE COMMITTEE MEMBERSHIP AND BOARD MEMBERS

On May 16, 2018, the Company announced that Michel de Rosen was appointed to the Company's Board of Directors, in replacement of George Horner III. Michel de Rosen's appointment was confirmed at the Company's Ordinary and Extraordinary General Meeting on June 22, 2018, in Montrouge, France. With this addition, DBV's Board is now comprised of eight directors.

On June 22, 2018, the Company announced that Joan Schmidt, our current Chief Legal Officer, was appointed as the Company's Executive Vice President, General Counsel. She is responsible for all legal affairs and compliance at DBV, reporting to the Deputy Chief Executive Officer, David Schilansky. Joan Schmidt also serves as a member of the Executive Committee.

On July 26, 2018, the Company announced the appointment of Kevin Trapp as the Company's Chief Commercial Officer. Kevin Trapp is responsible for all worldwide commercial functions at DBV Technologies, including the potential launch of the Company's lead product candidate, Viaskin® Peanut.

On November 16, 2018, the Company announced that its Board of Directors unanimously appointed Daniel Tassé as its Chief Executive Officer ("CEO"), effective November 29, 2018. Dr. Pierre-Henri Benhamou, who co-founded the Company in 2002, retired as CEO and currently serves as Non-Executive Chairman of the Board of Directors.

**Note 2: General Information and Statement of Compliance**

*Preliminary remarks*

DBV Technologies Inc. was incorporated in Delaware on April 7, 2015 (the "US subsidiary"). The share capital of this US subsidiary is 100% owned by DBV Technologies S.A. ("DBV Technologies").

DBV Australia Pty Ltd. was incorporated in New South Wales, Australia on July 3, 2018 (the "Australian subsidiary"). The share capital of this Australian subsidiary is 100% owned by DBV Technologies S.A. ("DBV Technologies").

DBV Canada Ltd. was incorporated in Ottawa, Ontario on August 13, 2018 (the "Canadian subsidiary"). The share capital of this Canadian subsidiary is 100% owned by DBV Technologies S.A. ("DBV Technologies").

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

*General principles*

The accompanying consolidated financial statements and related notes (the "Financial Statements") present the operations of DBV Technologies S.A. and its subsidiaries (the "Group") as of December 31, 2018. The Company is a corporate venture under French law (*société anonyme*) and its registered office is located at 177/181 avenue Pierre Brossolette, 92210 Montrouge at December 31, 2018.

Our Financial Statements as of December 31, 2018 have been prepared under the responsibility of DBV Technologies' management. The Financial Statements were approved by the Board of Directors of DBV Technologies on March 31, 2019.

All amounts are expressed in thousands of euros, unless stated otherwise.

For consolidation purposes, DBV Technologies S.A. and its subsidiaries have prepared individual financial statements for the periods ended December 31, 2016, December 31, 2017 and December 31, 2018.

**Statement of Compliance**

Our Financial Statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board ("IASB") and whose application is mandatory for the year ended December 31, 2018. Comparative figures are presented for December 31, 2016 and 2017.

Due to the listing of the Company's ordinary shares on the Euronext Paris and in accordance with the European Union's regulation No. 1606/2002 of July 19, 2002, the financial statements of the Group are also prepared in accordance with IFRS, as adopted by the European Union ("EU").

The following amendments are mandatorily effective for annual periods beginning on or after January 1st, 2018:

- IFRS 15 – Revenue from Contracts with Customers;
- Amendments to IFRS 15 – Clarifications to IFRS 15 Revenue from contracts with customers;
- IFRS 9 – Financial Instruments;
- Amendments to IFRS 4 – Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts;
- Amendments to IFRS 2 – Classification and measurement of share-based payment transactions;
- Amendments to IAS 40 – Transfers of Investment Property;
- IFRIC 22 – Foreign Currency Transactions and Advance Consideration;
- Annual improvements – 2014-2016 cycle.

The impacts of the first-time application of IFRS 15 are described in detail in Note 3.12. The impact from the fist-time adoption of IFRS 9 resulted in the change in accounting category, from "fair value to "amortised at cost" for the financial assets on the balance sheet. There is no valuation impact on IFRS 9 given the nature of the assets. The other standards and amendments have not had any impact on the Financial Statements as of December 31, 2018.

As of December 31, 2018, there are no differences in the IFRS published and mandated by the IASB and EU. As a result, the Financial Statements comply with IFRS as published by the IASB and as adopted by the EU.

IFRS include International Financial Reporting Standards ("IFRS"), International Accounting Standards (the "IAS"), as well as the interpretations issued by the Standing Interpretations Committee (the "SIC"), and the International Financial Reporting Interpretations Committee ("IFRIC"). The main accounting methods used to prepare the Financial Statements are described below. These methods were used for all years presented.

The Company did not elect for early application of the new standards, amendments and interpretations which were adopted but not mandatory as of December 31, 2018:

- IFRS 16 – Leases;
- Amendments to IFRS 9 – Prepayment features with negative compensation;
- IFRIC 23 – Uncertainty over Income Tax Treatments.

Management assessment concludes that the application of these standards and amendments would not have any impact on the Company's results on financial position or cash flows.

New and revised standards and amendments that may be relevant to the Company's operations but are not yet effective:

- Amendments to IFRS 4 – Applying IFRS 9 with IFRS 4;
- IFRS 16 – Leases;
- IFRS 17 – Insurance contracts;
- IFRS 14 – Regulatory deferral accounts;
- IFRIC 23 – Uncertainty over Income Tax Treatments.

With respect to the application of IFRS 16 on leases, the Group carried out preliminary analyses and it intends to apply the modified retrospective approach, resulting in an estimated increase in its financial liabilities of approximately 25 to 30 million euros.

Management is in the process of evaluating the impact of the other standards and amendments and is therefore, not currently able to estimate reliably the impact of their adoption on the Company's results on financial position or cash flows.

The accounting policies and measurement principles adopted for the Financial Statements as of and for the year ended December 31, 2018 are the same as those used as of and for the years ended December 31, 2016 and 2017, exept for the first application of IFRS 15 as described in detail in Note 3.12.

**Note 3: Accounting Principles**

*Going concern*

To date, we have not generated any product revenue and we continue to prepare the potential launch of our Viaskin® Peanut product candidate in North America planned in 2020 for which its BLA submission to the US FDA is expected in the third quarter of 2019. We expect operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support our operating plan for the next 12 months despite additional funds raised in March 2018. We expect to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding our ability to continue as a going concern.

We expect to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether we will be able to achieve these financing objectives.

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

Refer to the liquidity risk disclosed in Note 23.

*Methods of consolidation*

The Financial Statements incorporate the standalone financial statements of DBV Technologies S.A and its subsidiaries which are controlled by the Company. Control is achieved when the Company:

- has power over the subsidiary;
- is exposed, or has rights, to variable returns from its involvement with the subsidiary; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls a subsidiary if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

Consolidation of subsidiaries begins when the Company obtains control over the subsidiary and ceases when the Company loses control over the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the owners of the Company and to the non- controlling interests. Total comprehensive income of subsidiaries is attributed to the owners of the Company and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

When necessary, adjustments are made to the financial statements of subsidiaries to align their accounting policies with the Group's accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are neutralized in consolidation.

*Translation of financial statements in foreign currencies*

In preparing the financial statements of each individual group entity, transactions in currencies other than the entity's functional currency are recognized at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items carried at fair value that are denominated in foreign currencies are retranslated at the rates prevailing at the date when the fair value was determined.

For the purpose of presenting these consolidated financial statements, the assets and liabilities of the Group's foreign operations are translated into euros using exchange rates prevailing at the end of each reporting period. Income and expense items are translated at the average exchange rates at the dates of the transactions. Exchange differences arising, if any, are recognized in other comprehensive income and accumulated in equity.

***3.1 Intangible Assets***

In application of the provisions in IAS 38 *Intangible Assets* ("IAS 38"), intangible assets acquired are recorded as assets on the Consolidated Statements of Financial Position at their acquisition cost.

*Research and Development Expenses*

Research expenses are recorded in the Financial Statements as expenses.

In accordance with IAS 38, development expenses are recorded in the Financial Statements as intangible assets only if all the following criteria are met:

(a) technical feasibility necessary for the completion of the development project;

(b) intention on the part of the Company to complete the project and to utilize it;

(c) capacity to utilize the intangible asset;

(d) proof of the probability of future economic benefits associated with the asset;

(e) availability of the technical, financial, and other resources for completing the project; and

(f) reliable evaluation of the development expenses.

Because of the risks and uncertainties related to regulatory authorizations and to the research and development process, the Company believes that the six criteria stipulated by IAS 38 are only fulfilled once the Market Access Authorization has been obtained from the competent authorities.

The application of this principle has resulted in all development costs being expensed as incurred.

*Software*

The costs related to the acquisition of licenses to software are posted to assets on the basis of the costs incurred to acquire and to implement the software in question.

They are amortized using the straight-line method over a period of one to three years depending on the anticipated period of use.

***3.2 Property, Plant, and Equipment***

Property, plant, and equipment are recorded at their acquisition cost or, if applicable, at their production cost.

Property, plant, and equipment are depreciated on the basis of the straight-line method over the estimated use period of the property. The fixtures of property rented are depreciated over the term of their own lifetime or of the term of the rental agreement, whichever is shorter.

The depreciation periods used are the following:

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

***3.3 Financial Assets***

IFRS 9 replaces IAS 39—Financial Instruments: Recognition and Measurement. IFRS 9 defines the rules applicable to the classification and recognition of financial instruments, the impairment of financial assets (using a model of expected losses to replace the model of losses incurred) as well as hedge accounting. This new standard is mandatorily effective for annual periods beginning on or after January 1st, 2018. The Company did not elect for early application of IFRS 9.

As part of the application of IFRS 9, the Company reviewed the method of accounting for financial instruments that were previously classified as "Available-for-sale financial assets". These instruments are now recognized as "financial assets at fair value through *profit or loss*".

The Company do not hold any hedging instrument as of January 1, 2018 and as of December 31, 2018.

As of December 31, 2018, financial assets can be classified into three categories:

*Financial assets at amortized cost*

Financial assets at amortized cost are mainly cash and cash equivalent, loans and receivables, measured at amortized cost using the effective interest rate method, adjusted for expected credit losses and at initial recognition at their fair value (acquisition cost and transaction costs).

Interest recognized at the effective interest rate is recognized under "Other financial income and expenses" in the statement of profit and loss.

*Financial assets at fair value through profit or loss:*

Financial assets at fair value through profit or loss is comprised of:

- instruments whose contractual cash flows represent payments of interest or repayments of principal, but which are managed other than with a view to collecting cash flows and/or selling the asset;
- instruments that management has designated as 'fair value through profit or loss" on initial recognition.

Gains and losses arising from changes in fair value are recognized in profit or loss within the line items Financial income or Financial expenses.

*Financial assets at fair value through other comprehensive income mainly comprise:*

Financial assets at fair value through other comprehensive income is mainly comprised is composed of debt instruments whose contractual cash flows represent payments of interest or repayments of principal, and which are managed with a view to collecting cash flows and selling the asset. Gains and losses arising from changes in fair value are recognized in equity within the statement of comprehensive income in the period in which they occur. When such assets are derecognized, the cumulative gains and losses previously recognized in equity are reclassified to profit or loss for the period within the line items Financial income or Financial expenses. The Company does not hold this type of instrument as of January 1, 2018 and as of December 31, 2018.

*Impairment of financial assets measured at amortized cost*

The Company considers that a financial asset is impaired according to the expected loss method in order to take into account any defaults during the asset holding period. The amount of the expected loss is recognized in the balance sheet. Impairment losses are recognized in profit or loss.

***3.4 Recoverable Amount of the Intangible Assets and Property, Plant, and Equipment***

The property, plant, and equipment and intangible assets that have an established lifetime are subjected to an impairment test when the recoverability of their book value is called into question by the existence of indications of impairment. An impairment is posted to the accounts up to the amount of the excess of the book value over the recoverable value of the asset. The recoverable value of an asset corresponds to its fair value minus the costs of sale or its use value, whichever is higher.

***3.5 Inventories and Work in Progress***

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

Depreciation may be recorded on finished goods and work in progress (i) if their production value is greater than their net realizable value, we estimate that the estimated costs for finalization and the estimated costs for the sale, or (ii) if certain products are no longer used by the company, otherwise they are perishable.

At December 31, 2018, inventories were exclusively composed of work in progress relating to the production of the first batches that may be used for the commercialization and secondly to requalified batches that are not intended to be commercialized, which were fully depreciated.

***3.6 Share Capital***

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

***3.7 Payments in Shares***

Since its incorporation, the Company has established several plans for compensation paid in equity instruments in the form of employee warrants (*bons de souscription de parts de créateur d'entreprise* or *"*BSPCEs") granted to employees and/or executives and in the form of "share warrants" (*bons de souscription d'actions* or "BSAs") granted to non-employee members of the Board of Directors and scientific consultants.

Pursuant to IFRS 2 *Share-based payment* ("IFRS 2"), the cost of the transactions paid with equity instruments is posted to the accounts as an expense in exchange for an increase in the Shareholders' Equity for the period during which the rights to be benefited from the equity instruments are acquired.

The Company has applied IFRS 2 to all equity instruments granted since 2002 to corporate officers, members of the Scientific Committee and employees of the Company, as well as to certain persons bound by a service or investment contract. consultant to the Company.

The options are not subject to any market conditions. The characteristics of the options are presented in Note 17.

***3.9 Recognition and measurement of Financial Liabilities***

*Non-derivative financial liabilities*

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

*Borrowings and debt*

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs. Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within Financial expenses in the income statement over the term of the debt using the effective interest method.

***3.10 Subsidies and Conditional Advances***

*Subsidies*

The Company receives assistance in the form of subsidies, which are grants that are not repayable by the Company. The subsidies are recognized when there is reasonable assurance that:

- the Company will comply with the conditions attached to the subsidies, and
- the subsidies will be received.

Subsidies that are upfront non-refundable payments are presented as deferred revenue and recognized ratably through income over the duration of the research program to which the subsidy relates.

A public subsidy that is to be received (e.g. from OSEO, the French Agency for Innovation) either as compensation for expenses or for losses already incurred, or for immediate financial support of the Company without associated expenses or losses, is recognized as other income ratably over the duration of the funded project.

*Conditional advances*

The Company also receives from time to time assistance in the form of conditional advances, which are advances repayable in whole or in part based upon acknowledgment by the funder of a technical or commercial success of the related project by the funding entity. The details concerning the conditional advances are provided in Note 11.

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

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

The conditional advances that can be subject to this type of modification are the with Compagnie Française d'Assurance pour le Commerce Extérieur ("COFACE") advances presented in Note 11. The agreement with COFACE terminated on December 31, 2016.

***3.11 Provisions***

*Provisions for Risks and Expenses*

The provisions for risks and lawsuits correspond to the commitments resulting from lawsuits and various risks whose due dates and amounts are uncertain.

A provision is posted to the accounts when the Company has a legal or implicit obligation to a third party resulting from a past event, concerning which it is likely or certain that it will cause an outflow of resources to that third party, without consideration that is anticipated to be at least equivalent to the latter, and that the future outflows of liquid assets can be estimated reliably.

The amount recorded in the accounts as a provision is the best estimation of the expenses necessary to extinguish the obligation.

*Pension Retirement Obligations*

The employees of the Company receive the retirement benefits stipulated by law in France:

- obtaining a compensation paid by the Company to employees upon their retirement (defined-benefit plan);
- payment of retirement pensions by the Social Security agencies, which are financed by the contributions made by companies and employees (defined-contribution plans).

For the defined-benefit plans, the costs of the retirement benefits are estimated by using the projected credit unit method. According to this method, the cost of the retirement pensions is recognized in the Consolidated Statement of (Loss) so that it is distributed uniformly over the term of the services of the employees. The retirement benefit commitments are valued at the current value of the future payments estimated using, for the discounting, the market rate based on the long-term obligations of the first-category companies with a term that corresponds to that estimated for the payment of the services provided.

The Company relies on external actuaries to conduct an annual review of the valuation of these plans.

The difference between the amount of the provision at the beginning of a fiscal year and at the close of that year is recognized through profit or loss for the portion representing the costs of services rendered and through other comprehensive income for the portion representing the actual gains and losses.

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

***3.12 Revenue***

IFRS 15 became applicable on January 1, 2018, requiring the Company to update its accounting policies on revenue.

The concepts of "transfer of control," which is used primarily to determine the date of revenue recognition, and "performance obligations" do not call for any change in the accounting treatment of the Company's contracts. The concept of "variable consideration" does not materially alter the principles and methods used to measure net sales.

***3.13 Other Income***

*Subsidies*

Since it was formed, because of its innovative character, the Company has received a certain number of sources of assistance or subsidies from the central government or from local public authorities such as OSEO or the Banque Publique d'Investissement, intended to finance its operations or the recruitment of specific personnel.

When the obtention of the subsidy is reasonably certain, these subsidies are recognized as "Other income" during the calendar year over which the corresponding expenses or expenditures were recorded.

*Research Tax Credit*

The Research Tax Credit (*Crédit d'Impôt Recherche,* CIR) is granted to companies by the French tax authorities in order to encourage them to conduct technical and scientific research. Companies that prove that they have expenditures that meet the required criteria (research expenditures located in France or, since January 1, 2005, within the European Community or in another State that is a party to the Agreement on the European Economic Area that has concluded a tax treaty with France that contains an administrative assistance clause) receive a tax credit that can be used for the payment of the corporate tax due for the fiscal year in which the expenditures were made and the next three fiscal years, or, as applicable, can be reimbursed for the excess portion. The expenditures taken into account for the calculation of the research tax credit involve only research expenses.

The Company has received the Research Tax Credit annually since it was formed.

The Company received the reimbursement of the 2015 Research Tax Credit for an amount of €5.7 million during the year 2016.

The Company received the reimbursement of the 2016 Research Tax Credit for an amount of €7.3 million during the year 2017.

The Company received the reimbursement of the 2017 Research Tax Credit for an amount of €9.5 million during the year 2018.

The Company will request the reimbursement of the 2018 Research Tax Credit for an amount of €10.8 million during the year 2019, under the community tax rules for small and medium firms in compliance with the regulatory texts applicable.

*Collaboration agreement with Nestlé Health Science*

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

Regarding the first application of IFRS 15 on January 1, 2018, an analysis has been completed on performance conditions, revenue recognition method for milestones payment and on the sale price allocation for the collaboration contract signed with Nestlé in 2016. It has been determined that the license and developments to be made by the Company are a unique performance obligation.

As a result, the Company has concluded that under IFRS 15, revenue related to the contract will be recognized progressively, up to the costs incurred by the Company at the end of 2018. No margin is recognized at this stage of the development. Deferred revenue is recognized and reversed over the period in which there is a contractual obligation.

This this agreement is not considered an onerous contract for the year-ended December 31,2018.

As a result, the application of IFRS 15 had no impact on the financial statements as at December 31, 2018, and retrospectively as at December 31, 2017.

***3.14 Rental Agreements***

The rental agreements involving property, plant, and equipment are classified as finance lease agreements when the Company bears a substantial portion of all the benefits and risks inherent in the ownership of the property. The assets that are covered under financing lease agreements are capitalized as of the beginning date of the rental agreement on the basis of the fair value of the rented asset or the discounted values of the future minimum payments, whichever is lower. Each rental payment is distributed between the debt and the financial cost in such a manner as to determine a constant interest rate on the principal that remains due. The corresponding rental obligations, net of the financial expenses, are classified as financial liabilities. The portion of the financial expense that corresponds to the interest is recognized as an expense over the term of the agreement. The property, plant, or equipment acquired within the framework of a finance lease agreement is amortized over the use period or the term of the lease agreement, whichever is shorter.

The rental agreements for which a significant portion of the risks and advantages is preserved by the lessor are classified as ordinary rental agreements. The payments made for these ordinary rental agreements, net of any incentive measures, are recognized as expenses on the income statement in a linear manner over the term of the agreement.

***3.15 Taxes***

*Income Tax*

Deferred taxes are recognized for all the temporary differences arising from the difference between the tax basis and the accounting basis of the assets and liabilities that appear in the financial statements. The primary temporary differences are related to the tax losses that can be carried forward or backward. The tax rates that have been ratified by a legal text as of the closing date are utilized to determine the deferred taxes.

The deferred tax assets are recorded in the accounts only to the extent that it is likely that the future profits will be sufficient to absorb the losses that can be carried forward or backward. Considering its stage of development, which does not allow income projections judged to be sufficiently reliable to be made, the Company has not recognized deferred tax assets in relation to tax losses carryforward in the Consolidated Statements of Financial Position.

### *3.16 Segment Information*

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

### *3.17 Other Items in the Comprehensive (or Loss)*

The revenue and expense items for the period that are not posted in the Consolidated Statements of (Loss) as stipulated by the applicable standards are presented, as necessary, under the rubric "Other items in the comprehensive (or loss)."

### *3.18 Use of Estimates*

The preparation of our Financial Statements requires the management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. Estimates and assumptions are based on historical experience and other factors that management believes to be reasonable under the circumstances. Estimates and assumptions are measured on an ongoing basis. Actual results may differ from these estimates.

These estimates and judgments mainly involve:

- an estimate of time and costs required to complete the collaboration agreement with Nestlé Health Science;
- a valuation of the fair value of the employee warrants (BSPCEs) granted to employees and/or executives and share warrants (BSAs) granted to non-employee members of the Board of Directors and scientific consultants and to service providers, performed on the basis of actuarial models; these models require the use by the Company of certain calculation assumptions such as the expected volatility of the security and assumptions concerning the achievement of performance criteria;
- an estimate of the expected dates of achievement of the performance conditions for the duration of the spillover from the granting of stock options and free shares;
- an estimate of the Research Tax Credit based on internal and external expenses incurred by the Company during the year. Only eligible research expenses are included in the calculation of the research tax credit;
- an estimate of provisions.

### *3.19 Presentation of Financial Assets and Financial Liabilities Measured at Fair Value*

In accordance with the amendments to IFRS 7, financial instruments are presented in three categories based on a hierarchical method used to determine their fair value:

- level 1: fair value calculated using quoted prices in an active market for identical assets and liabilities;
- level 2: fair value calculated using valuation techniques based on observable market data such as prices of similar assets and liabilities or parameters quoted in an active market;
- level 3: fair value calculated using valuation techniques based wholly or partly on unobservable inputs such as prices in an inactive market or a valuation based on multiples for unlisted securities.

### *3.20 Subsequent events*

The Consolidated Statements of Financial Position and the Consolidated Statements of (Loss) of the Company are adjusted to reflect the subsequent events that alter the amounts related to the situations that exist as of the closing date. The adjustments are made until the date the financial statements are approved and authorized for issuance by the Board of Directors.

**Note 4: Intangible Assets**

The intangible assets are broken down as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Patents, licenses, trademarks | 196 | 414 | 201 |
| Software | 376 | 450 | 703 |
| **Total historical cost** | **572** | **864** | **905** |
| Accumulated amort. of patents, licenses, and trademarks | (125) | (340) | (200) |
| Accumulated depreciation of software packages | (351) | (401) | (675) |
| **Accumulated amortization and depreciation** | **(476)** | **(741)** | **(875)** |
| **Net total** | **96** | **123** | **29** |

There has been no recognition of impairment losses in application of IAS 36 *Impairment of Assets* for the calendar years presented.

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

| | 1/1/2016 | Increase | Decrease | 12/31/2016 |
|---|---|---|---|---|
| | | (Amounts in thousands of Euros) | | |
| Laboratory equipment | 2,357 | 740 | — | 3,097 |
| Building fixtures | 938 | 3,672 | — | 4,610 |
| Office equipment | 209 | 398 | — | 607 |
| Computer equipment | 470 | 516 | — | 986 |
| Property, plant, and equipment in progress | 3,672 | 2,713 | — | 6,385 |
| **Total, gross** | **7,646** | **8,039** | **—** | **15,685** |
| Accumulated depreciation of laboratory equipment | 948 | 557 | — | 1,505 |
| Accumulated depreciation of the building fixtures | 782 | 327 | — | 1,109 |
| Accumulated depreciation of office equipment | 131 | 81 | — | 212 |
| Accumulated depreciation of computer equipment | 205 | 172 | — | 377 |
| **Total accumulated amortization and depreciation** | **2,065** | **1,137** | **—** | **3,203** |
| **Total, net** | **5,581** | **6,901** | **—** | **12,482** |

| | 1/1/2017 | Increase | Decrease | 12/31/2017 |
|---|---|---|---|---|
| | | (Amounts in thousands of Euros) | | |
| Laboratory equipment | 3,097 | 2,806 | (83) | 5,820 |
| Building fixtures | 4,610 | 534 | (46) | 5,098 |
| Office equipment | 607 | 275 | (116) | 766 |
| Computer equipment | 986 | 116 | (30) | 1,073 |
| Property, plant, and equipment in progress | 6,385 | 3,384 | (55) | 9,714 |
| **Total, gross** | **15,685** | **7,114** | **(329)** | **22,470** |
| Accumulated depreciation of laboratory equipment | 1,505 | 802 | (63) | 2,244 |
| Accumulated depreciation of the building fixtures | 1,109 | 484 | (14) | 1,580 |
| Accumulated depreciation of office equipment | 212 | 213 | (105) | 320 |
| Accumulated depreciation of computer equipment | 377 | 172 | (30) | 520 |
| **Total accumulated amortization and depreciation** | **3,202** | **1,671** | **(211)** | **4,663** |
| **Total, net** | **12,482** | **5,443** | **(118)** | **17,808** |

| | 1/1/2018 | Increase | Decrease | 12/31/2018 |
|---|---|---|---|---|
| | (Amounts in thousands of Euros) | | | |
| Laboratory equipment | 5,820 | 6,305 | (12) | 12,113 |
| Building fixtures | 5,098 | 133 | — | 5,231 |
| Office equipment | 766 | 25 | — | 790 |
| Computer equipment | 1,073 | 434 | — | 1,507 |
| Property, plant, and equipment in progress | 9,714 | 7,623 | (9,750) | 7,587 |
| **Total, gross** | **22,470** | **14,520** | **(9,762)** | **27,228** |
| Accumulated depreciation of laboratory equipment | 2,244 | 1,567 | — | 3,811 |
| Accumulated depreciation of the building fixtures | 1,580 | 352 | (12) | 1,919 |
| Accumulated depreciation of office equipment | 320 | 129 | — | 449 |
| Accumulated depreciation of computer equipment | 520 | 310 | — | 830 |
| **Total accumulated amortization and depreciation** | **4,663** | **2,358** | **(12)** | **7,009** |
| **Total, net** | **17,808** | **12,162** | **(9,750)** | **20,219** |

Over the three years presented, the acquisitions correspond primarily to building fixtures and to laboratory and production equipment and material. The investments made in the design and development of industrial machines have declined between the two periods following the completion of the setup of our main industrial machines (mainly Gen 4) in early 2018. The increase during 2018 of the property, plant, and equipment in progress is related to the purchase of materials for the design and development of industrial machinery (mainly Gen 3.2, 3.3 and 4Bis).

**Note 6: Non-Current Financial Assets**

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Deposits | 824 | 577 | 1,374 |
| Pledged securities and other non-current financial assets | 611 | 1,102 | 4,226 |
| Liquidity contract | 1,310 | 1,333 | 432 |
| **Total non-current financial assets** | **2,745** | **3,012** | **6,033** |

The non-current financial assets are composed of security deposits paid to premises' lessors, of pledged securities not used as of December 31, 2018 and the liquidity contract.

Under the liquidity contract, 41,159 treasury shares were allocated as a reduction of Shareholders' Equity as at December 31, 2018 with the cash balance being maintained in financial assets.

**Note 7: Inventories and Work in Progress**

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Inventories of raw materials | 69 | — | — |
| Work in progress | — | — | 2,338 |
| Allowance for inventory write-down (charged to income statement) | (69) | — | (772) |
| **Total net value of the inventories** | — | — | 1,566 |

As of December 31, 2016, the inventories and work in progress involved the Diallertest Milk product. The Company discontinued its commercial partnership with respect to the product during the second half of 2015. The inventories have been discarded during the year 2017.

As of December 31, 2018, inventories are exclusively composed of work in progress for €1,566 thousand relate to the production of the first batches potentially intended for the commercialization, if approved.

An allowance for inventory write-down was recorded at December 31, 2018 for non-commercial batches of Viaskin® Peanut.

**Note 8: Customer Accounts Receivable and Other Current Assets**

***8.1 Customer Accounts Receivable and Related Receivables***

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Accounts receivable | 1,263 | 1,265 | — |
| Valuation allowance (charged to income statement) | (13) | — | — |
| **Total net value of accounts receivable** | **1,250** | **1,265** | **—** |

All the customer accounts receivable have payment terms of less than one year.

As of December 31, 2016, and 2017, the accounts receivable corresponds primarily to the amounts due under the collaboration agreement with Nestlé Health Science.

***8.2 Other current assets***

The other current assets are broken down as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Research tax credit | 7,228 | 9,217 | 10,829 |
| Other tax claims | 2,618 | 5,258 | 4,292 |
| Other receivables | 1,883 | 1,192 | 1,745 |
| Prepaid expenses | 2,725 | 2,054 | 4,265 |
| **Total** | **14,454** | **17,721** | **21,131** |

The other tax debt claims are primarily related to the deductible VAT as well as the reimbursement of VAT that has been requested.

Prepaid expenses are comprised primarily of rental and insurance expenses, as well as legal and scientific consulting fees. Prepaid expenses also include upfront payments which are recognized over the term of the ongoing clinical studies.

*Research Tax Credit*

The Company benefits from the provisions in Articles 244 *quater* B and 49 *septies* F of the French Tax Code related to the Research Tax Credit. In compliance with the principles described in Note 3.13, the Research Tax Credit is posted to the accounts as “Other Income” during the year with which the eligible research expenditures are associated.

The changes in this Research Tax Credit over the last three years are presented as follows:

| | Amount in thousands of Euros |
|---|---|
| **Opening Balance Sheet Receivable as of January 1, 2016** | 5,702 |
| + Other income | 7,228 |
| - Payment received | (5,702) |
| - Adjustment | — |
| **Closing Balance Sheet Receivable as of December 31, 2016** | **7,228** |

| | Amount in thousands of Euros |
|---|---|
| **Opening balance sheet receivable as of January 1, 2017** | 7,228 |
| + Operating revenue | 9,217 |
| - Payment received | (7,341) |
| - Adjustement | 113 |
| **Closing balance sheet receivable as of December 31, 2017** | **9,217** |

| | Amount in thousands of Euros |
|---|---|
| **Opening balance sheet receivable as of January 1, 2018** | 9,217 |
| + Operating revenue | 10,829 |
| - Payment received | (9,479) |
| - Adjustement | 262 |
| **Closing balance sheet receivable as of December 31, 2018** | **10,829** |

Following a tax inspection led by the French tax authorities on fiscal years 2012, 2013 and 2014, the Company received on July 4, 2016 a proposition of adjustments primarily affecting the 2014 Research Tax credit. The proposed adjustment amounted to €0.9 million and had been accrued in the financial statements as of December 31, 2017.

On June 25, 2018, the Company received the final reassessment for €58 thousand. The accrual initially recognized for €0.9 million has been reversed in the December 31, 2018 financial statements.

A tax audit covering all the tax declarations for the period from January 1, 2015 to December 31, 2016, extended to December 31, 2017 for VAT, was conducted in the third quarter of 2018. The conclusions of this tax audit were received in November 2018 without major financial consequences for the Group.

**Note 9: Cash and Cash Equivalents**

The cash and cash equivalents item is broken down as follows (in thousands of Euros):

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Cash | 146,374 | 32,054 | 77,236 |
| Cash equivalent term deposits | 110,100 | 105,826 | 45,534 |
| **Total cash and cash equivalent as reported in statement of financial position** | **256,473** | **137,880** | **122,770** |
| Bank overdrafts | — | — | — |
| **Total net cash and cash equivalents as reported in the statement of cash flow** | **256,473** | **137,880** | **122,770** |

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

**Note 10: Capital**

***10.1 Share Capital Issued***

The share capital, as of December 31, 2018, is set at the sum of €3,015,777.70. It is divided into 30,157,777 fully authorized, subscribed and paid-up shares with a nominal value of €0.10.

This number does not include share warrants ("BSA"), employee warrants ("BSPCE"), stock-options ("SO") and performance shares ("AGA") granted to certain investors and to certain natural persons, both employees and non-employees of the Company.

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

The table below presents the historical changes in the share capital of the Company as of December 31, 2016 , 2017 and 2018:

| Date | Nature of the Transactions | Share Capital | Share premium | Number of Shares | Nominal value |
|---|---|---|---|---|---|
| | **Balance as of January 1, 2016** | K€ 2,420.5 | K€ 403,910.4 | 24,205,129 | € 0.10 |
| 01/05/16 | Capital increase by issuance of common shares | K€ 0.6 | K€ 32.7 | 6,495 | |
| 02/16/16 | Issue of share subscription warrants | K€ | K€ 471.1 | | € 0.10 |
| 04/06/16 | Capital increase by incorporation of reserve | K€ 10.2 | K€ (10.2) | 101,829 | € 0.10 |
| 05/27/16 | Capital increase by issuance of common shares | K€ 0.2 | K€ 7.5 | 1,500 | € 0.10 |
| 06/03/16 | Capital increase by issuance of common shares | K€ 15.6 | K€ (15.6) | 156,000 | € 0.10 |
| 06/06/16 | Capital increase by issuance of common shares | K€ 6.0 | K€ 301.2 | 59,890 | € 0.10 |
| 06/10/16 | Capital increase by issuance of common shares | K€ 3.5 | K€ 176.0 | 34,985 | € 0.10 |
| 07/18/16 | Capital increase by issuance of common shares | K€ 2.0 | K€ 100.7 | 20,010 | € 0.10 |
| 08/21/16 | Issue of share subscription warrants | K€ | K€ 106 | | € |
| 08/04/16 | Capital increase by issuance of common shares | K€ 1.0 | K€ 50.4 | 10,020 | € 0.10 |
| 08/24/16 | Capital increase by issuance of common shares | K€ 0.7 | K€ 37.1 | 7,380 | € 0.10 |
| 08/30/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 08/31/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/01/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/02/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/05/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/06/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/06/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/08/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/09/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/12/16 | Capital increase by issuance of common shares | K€ 0.4 | K€ 66.2 | 3,500 | € 0.10 |
| 09/12/16 | Capital increase by issuance of common shares | K€ 0.5 | K€ 23.1 | 4,590 | € 0.10 |
| 11/25/16 | Capital increase by issuance of common shares | K€ 0.6 | K€ 30.2 | 6,000 | € 0.10 |
| | **Balance as of December 31, 2016** | K€ 2,464.9 | K€ 405,882.5 | 24,648,828 | € 0.10 |

| Date | Nature of the Transactions | Share Capital | Share premium | Number of Shares | Nominal value |
|---|---|---|---|---|---|
| | **Balance as of January 1, 2017** | **K€ 2,464.9** | **K€405,882.5** | 24,648,828 | € 0.10 |
| 02/03/17 | Capital increase by issuance of common shares | K€ 2.0 | K€ 100.7 | 20,010 | € 0.10 |
| 02/09/17 | Issue of share subscription warrants | K€ | K€ 237.4 | | € |
| 05/16/17 | Capital increase by issuance of common shares | K€ 4.0 | K€ 170.7 | 40,365 | € 0.10 |
| 07/12/17 | Capital increase by issuance of common shares | K€ 0.2 | K€ 8.3 | 1,650 | € 0.10 |
| 08/04/17 | Capital increase by issuance of common shares | K€ 0.1 | K€ 64.6 | 1,200 | € 0.10 |
| 09/14/17 | Capital increase by issuance of common shares | K€ 3.6 | K€ 208.2 | 35,925 | € 0.10 |
| 09/14/17 | Issue of share subscription warrants | K€ | K€ 53.1 | | € |
| 09/29/17 | Capital increase by issuance of common shares | K€ 0.1 | K€ 4.0 | 500 | € 0.10 |
| 09/30/17 | Capital increase by incorporation of reserve | K€ 23.1 | K€ (23.1) | 230,843 | € 0.10 |
| 10/02/17 | Capital increase by issuance of common shares | K€ 0.1 | K€ 4.0 | 500 | € 0.10 |
| 12/15/17 | Capital increase by incorporation of reserve | K€ 1.1 | K€ (1.1) | 11,001 | € 0.10 |
| | **Balance as of December 31, 2017** | K€ 2,499.1 | K€406,709.3 | 24,990,822 | € 0.10 |

| Date | Nature of the Transactions | Share Capital | Share premium | Number of Shares | Nominal value |
|---|---|---|---|---|---|
| | **Balance as of January 1, 2018** | **K€ 2,499.1** | **K€406,709.3** | **24,990,822** | **€ 0.10** |
| 01/08/18 | Capital increase by issuance of common shares | K€ 0.7 | K€ 52.3 | 7,000 | € 0.10 |
| 01/09/18 | Capital increase by issuance of common shares | K€ 0.5 | K€ 25.2 | 5,010 | € 0.10 |
| 01/16/18 | Capital increase by issuance of common shares | K€ 2.0 | K€ 100.4 | 19,950 | € 0.10 |
| 01/18/18 | Capital increase by issuance of common shares | K€ 12.9 | K€ 963.6 | 129,000 | € 0.10 |
| 01/30/18 | Capital increase by issuance of common shares | K€ 1.3 | K€ 97.1 | 13,000 | € 0.10 |
| 01/31/18 | Capital increase by issuance of common shares | K€ 2.0 | K€ 149.4 | 20,000 | € 0.10 |
| 02/16/18 | Capital increase by incorporation of reserve | K€ 23.8 | K€ (23.8) | 238,337 | € 0.10 |
| 03/13/18 | Capital increase by incorporation of reserve | K€ 23.8 | K€ (23.8) | 238,319 | € 0.10 |
| 03/23/18 | Capital increase by issuance of common shares | K€ 352.8 | K€ 122,095.5 | 3,527,752 | € 0.10 |
| 03/26/18 | Capital increase by issuance of common shares | K€ 52.9 | K€ 18,314.3 | 529,162 | € 0.10 |
| 04/05/18 | Capital increase by issuance of common shares | K€ 1.2 | K€ 91.9 | 12,302 | € 0.10 |
| 04/06/18 | Capital increase by incorporation of reserve | K€ 5.8 | K€ (5.8) | 57,500 | € 0.10 |
| 04/06/18 | Capital increase by issuance of common shares | K€ 1.4 | K€ 105.6 | 14,138 | € 0.10 |
| 04/09/18 | Capital increase by issuance of common shares | K€ 0.4 | K€ 26.6 | 3,560 | € 0.10 |
| 04/16/18 | Capital increase by issuance of common shares | K€ 0.8 | K€ 88.0 | 7,500 | € 0.10 |
| 07/02/18 | Capital increase by incorporation of reserve | K€ 19.3 | K€ (19.3) | 193,000 | € 0.10 |
| 08/21/18 | Issue of share subscription warrants | K€ | K€ 163.7 | | € |
| 07/05/18 | Capital increase by issuance of common shares | K€ 3.3 | K€ 164.1 | 32,625 | € 0.10 |
| 07/11/18 | Capital increase by issuance of common shares | K€ 6.4 | K€ 478.1 | 64,000 | € 0.10 |
| 08/16/18 | Capital increase by incorporation of reserve | K€ 1.0 | K€ (1.0) | 10,000 | € 0.10 |
| 09/01/18 | Capital increase by incorporation of reserve | K€ 0.5 | K€ (0.5) | 5,000 | € 0.10 |
| 09/21/18 | Capital increase by issuance of common shares | K€ 0.5 | K€ 37.4 | 5,000 | € 0.10 |
| 10/27/18 | Capital increase by incorporation of reserve | K€ 1.5 | K€ (1.5) | 15,000 | € 0.10 |
| 12/09/18 | Capital increase by incorporation of reserve | K€ 2.0 | K€ (2.0) | 19,800 | € 0.10 |
| 12/31/18 | Fees charged to share premium | K€ | K€ (10,292.6) | | € |
| | **Balance as of December 31, 2018** | K€ 3,015.8 | K€539,292.0 | 30,157,777 | € 0.10 |

On March 20 and 21, 2018, the Company announced the launch and the price of an underwritten global offering of an aggregate of 3,527,752 new ordinary shares, in (i) a public offering of 1,392,015 ordinary shares in the form of 2,784,030 American Depositary Shares (ADSs, each ADS represents the right to receive one-half of one ordinary share) in the United States, Canada and certain other countries outside Europe and (ii) a concurrent private placement of 2,135,737 ordinary shares in Europe (including France).

In addition, the Company has granted the underwriters a 30-day option to purchase, on the same terms and conditions, up to 529,162 additional ordinary shares, which may be in the form of ADSs (the "Option").

The pricing of the underwritten global offering was set at (i) a public offering price of $21.26 per ADS in the United States, Canada and certain other countries outside Europe (based on an exchange rate of $1.2246=€1.00) and at (ii) a public offering price of €34.71 per ordinary share in Europe (including France). The price of the global offering is equal to the volume weighted-average of the trading prices of the Company's ordinary shares on Euronext Paris over the three (3) trading days prior to the launch of the global offering less a discount of 4.99%.

On March 23, 2018, the Company announced the closing of the underwritten global offering of new ordinary shares and Full Exercise of Underwriters' Option to Purchase Additional Shares. The issuance and the settlement and delivery of the new ordinary shares on Euronext Paris took place on March 26, 2018.

As part of the closing of the underwritten global offering of new ordinary shares and Full Exercise of Underwriters' Option public offering, share capital increased by the issuance of 4,056,914 shares (K€405.7) with a corresponding increase of €130.1 million in share premium (€140.4 million gross, or €130.1 million net after deduction of fees and expenses of €10.3 million).

No fees and banks commissions related to share capital increases in 2016 and 2017 were posted in deduction of the share premium.

***10.2 Share Warrants and Employee Warrants***

The Company has issued share warrants (BSAs), employee warrants (BSPCEs), performance shares (AGAs) and stock-options (SO) as follows:

| Date | Type | Number of warrants issued as of 12/31/2016 | Number of warrants null and void as of 12/31/2016 | Number of warrants null and outstanding as of 12/31/2016 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 12/07/2007 | BSA | 1,717 | 572 | 859 | 12,885 | € 4.33 |
| 01/21/2009 | BSA/BSPCE | 16,380 | — | 2,997 | 44,955 | € 4.33 |
| 01/21/2009 | BSPCE | 2,296 | — | — | — | € 4.33 |
| 06/25/2010 | BSA | 1,825 | — | 730 | 10,950 | € 4.33 |
| 01/28/2011 | BSA | 10,039 | 7,529 | — | — | € 5.13 |
| 06/24/2011 | BSA/BSPCE | 32,000 | — | 10,440 | 156,600 | € 5.13 |
| 11/22/2011 | BSA/BSPCE | 11,377 | — | 2,509 | 37,635 | € 5.13 |
| 01/17/2012 | BSA | 89,835 | — | — | — | € 5.13 |
| 04/02/2012 | AGA | 669,796 | 1,860 | — | — | € — |
| 07/25/2012 | AGA | 134,081 | — | — | — | € — |
| 09/25/2012 | BSA | 30,000 | — | 10,000 | 10,000 | € 8.59 |
| 11/28/2012 | AGA | 35,360 | — | — | — | € — |
| 07/25/2013 | BSA | 73,000 | — | 13,000 | 13,000 | € 8.10 |
| 09/12/2013 | AGA | 501,500 | 113,333 | — | — | € — |
| 09/18/2013 | SO | 518,000 | 47,000 | 471,000 | 471,000 | € 7.57 |
| 06/03/2014 | BSA | 10,000 | — | 5,000 | 5,000 | € 18.79 |
| 06/03/2014 | AGA | 186,000 | 30,000 | — | — | € — |

| Date | Type | Number of warrants issued as of 12/31/2016 | Number of warrants null and void as of 12/31/2016 | Number of warrants null and outstanding as of 12/31/2016 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 06/03/2014 | SO | 75,000 | — | 40,000 | 40,000 | € 19.01 |
| 03/24/2015 | BSA | 10,000 | — | 10,000 | 10,000 | € 43.00 |
| 06/23/2015 | SO | 120,000 | — | 120,000 | 120,000 | € 48.90 |
| 09/30/2015 | AGA | 708,500 | 13,000 | 695,500 | 695,500 | € — |
| 11/19/2015 | SO | 195,000 | 25,000 | 170,000 | 170,000 | € 66.06 |
| 11/19/2015 | BSA | 22,500 | 7,500 | 15,000 | 15,000 | € 66.06 |
| 12/15/2015 | AGA | 42,000 | 6,000 | 36,000 | 36,000 | € — |
| 12/15/2015 | BSA | 90,000 | 16,500 | 73,500 | 73,500 | € 64.14 |
| 01/04/2016 | SO | 75,000 | — | 75,000 | 75,000 | € 65.68 |
| 04/06/2016 | AGA | 63,750 | 5,000 | 58,750 | 58,750 | € — |
| 04/21/2016 | SO | 33,000 | — | 33,000 | 33,000 | € 62.82 |
| 05/02/2016 | SO | 22,000 | — | 22,000 | 22,000 | € 59.04 |
| 06/21/2016 | SO | 110,000 | — | 110,000 | 110,000 | € 53.96 |
| 06/21/2016 | BSA | 20,000 | — | 20,000 | 20,000 | € 52.97 |
| 06/21/2016 | AGA | 208,000 | — | 208,000 | 208,000 | € — |
| 08/01/2016 | SO | 10,000 | — | 10,000 | 10,000 | € 62.24 |
| 09/15/2016 | SO | 9,300 | — | 9,300 | 9,300 | € 62.80 |
| 10/17/2016 | SO | 16,500 | — | 16,500 | 16,500 | € 64.39 |
| 10/27/2016 | AGA | 15,000 | — | 15,000 | 15,000 | € — |
| 11/15/2016 | SO | 8,300 | — | 8,300 | 8,300 | € 68.33 |
| 12/09/2016 | SO | 74,960 | — | 74,960 | 74,960 | € 69.75 |
| 12/09/2016 | AGA | 23,600 | — | 23,600 | 23,600 | € — |
| **Total** | | **4,275,616** | **273,294** | **2,360,945** | **2,606,435** | |

| Date | Type | Number of warrants issued as of 12/31/2017 | Number of warrants null and void as of 12/31/2017 | Number of warrants null and outstanding as of 12/31/2017 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 12/07/2007 | BSA | 1,717 | 572 | — | — | € 4.33 |
| 01/21/2009 | BSA/BSPCE | 16,380 | — | — | — | € 4.33 |
| 01/21/2009 | BSPCE | 2,296 | — | — | — | € 4.33 |
| 06/25/2010 | BSA | 1,825 | — | — | — | € 4.33 |
| 01/28/2011 | BSA | 10,039 | 7,529 | — | — | € 5.13 |
| 06/24/2011 | BSA/BSPCE | 32,000 | — | 8,996 | 134,940 | € 5.13 |
| 11/22/2011 | BSA/BSPCE | 11,377 | — | 2,509 | 37,635 | € 5.13 |
| 01/17/2012 | BSA | 89,835 | — | — | — | € 5.13 |
| 04/02/2012 | AGA | 669,796 | 1,860 | — | — | € — |
| 07/25/2012 | AGA | 134,081 | — | — | — | € — |
| 09/25/2012 | BSA | 30,000 | — | 7,500 | 7,500 | € 8.59 |
| 11/28/2012 | AGA | 35,360 | — | — | — | € — |
| 07/25/2013 | BSA | 73,000 | — | 9,500 | 9,500 | € 8.10 |
| 09/12/2013 | AGA | 501,500 | 113,333 | — | — | € — |
| 09/18/2013 | SO | 518,000 | 47,000 | 471,000 | 471,000 | € 7.57 |
| 06/03/2014 | BSA | 10,000 | — | 2,500 | 2,500 | € 18.79 |

| Date | Type | Number of warrants issued as of 12/31/2017 | Number of warrants null and void as of 12/31/2017 | Number of warrants null and outstanding as of 12/31/2017 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 06/03/2014 | AGA | 186,000 | 30,000 | — | — | € — |
| 06/03/2014 | SO | 75,000 | — | 40,000 | 40,000 | € 19.01 |
| 03/24/2015 | BSA | 10,000 | — | 10,000 | 10,000 | € 43.00 |
| 06/23/2015 | SO | 120,000 | — | 120,000 | 120,000 | € 48.90 |
| 09/30/2015 | AGA | 708,500 | 23,000 | 454,657 | 454,657 | € — |
| 11/19/2015 | SO | 195,000 | 25,000 | 170,000 | 170,000 | € 66.06 |
| 11/19/2015 | BSA | 22,500 | 7,500 | 15,000 | 15,000 | € 66.06 |
| 12/15/2015 | AGA | 42,000 | 9,000 | 21,999 | 21,999 | € — |
| 12/15/2015 | BSA | 90,000 | 16,500 | 73,500 | 73,500 | € 64.14 |
| 01/04/2016 | SO | 75,000 | — | 75,000 | 75,000 | € 65.68 |
| 04/06/2016 | AGA | 63,750 | 6,250 | 57,500 | 57,500 | € — |
| 04/21/2016 | SO | 33,000 | — | 33,000 | 33,000 | € 62.82 |
| 05/02/2016 | SO | 22,000 | — | 22,000 | 22,000 | € 59.04 |
| 06/21/2016 | SO | 110,000 | 7,500 | 101,300 | 101,300 | € 53.96 |
| 06/21/2016 | BSA | 20,000 | — | 20,000 | 20,000 | € 52.97 |
| 06/21/2016 | AGA | 208,000 | — | 208,000 | 208,000 | € — |
| 08/01/2016 | SO | 10,000 | — | 10,000 | 10,000 | € 62.24 |
| 09/15/2016 | SO | 9,300 | — | 9,300 | 9,300 | € 62.80 |
| 10/17/2016 | SO | 16,500 | 7,200 | 9,300 | 9,300 | € 64.39 |
| 10/27/2016 | AGA | 15,000 | — | 15,000 | 15,000 | € — |
| 11/15/2016 | SO | 8,300 | — | 8,300 | 8,300 | € 68.33 |
| 12/09/2016 | SO | 74,960 | 2,000 | 72,000 | 72,000 | € 69.75 |
| 12/09/2016 | AGA | 23,600 | 1,900 | 21,700 | 21,700 | € — |
| 12/09/2016 | BSA | 59,000 | 24,992 | 34,008 | 34,008 | € 69.75 |
| 12/15/2016 | SO | 1,100 | — | 1,100 | 1,100 | € 69.35 |
| 01/16/2017 | SO | 19,100 | — | 19,100 | 19,100 | € 66.11 |
| 03/14/2017 | AGA | 22,500 | 2,500 | 20,000 | 20,000 | € — |
| 03/15/2017 | SO | 7,200 | — | 7,200 | 7,200 | € 66.25 |
| 04/18/2017 | SO | 16,500 | — | 16,500 | 16,500 | € 60.77 |
| 04/20/2017 | AGA | 24,000 | — | 24,000 | 24,000 | € — |
| 06/15/2017 | SO | 126,000 | 7,500 | 118,500 | 118,500 | € 59.05 |
| 06/15/2017 | SO | 111,600 | — | 111,600 | 111,600 | € 60.54 |
| 06/15/2017 | BSA | 9,000 | — | 9,000 | 9,000 | € 59.05 |
| 07/17/2017 | SO | 30,900 | — | 30,900 | 30,900 | € 71.61 |
| 09/15/2017 | SO | 52,600 | — | 52,600 | 52,600 | € 74.22 |
| 12/05/2017 | SO | 625,200 | — | 625,200 | 625,200 | € 39.00 |
| 12/15/2017 | SO | 8,300 | — | 8,300 | 8,300 | € 38.08 |
| **Total** | | **5,388,616** | **341,196** | **3,148,469** | **3,309,539** | |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 12/07/2007 | BSA | 1,717 | 572 | — | — | € 4.33 |
| 01/21/2009 | BSA/BSPCE | 16,380 | — | — | — | € 4.33 |
| 01/21/2009 | BSPCE | 2,296 | — | — | — | € 4.33 |
| 06/25/2010 | BSA | 1,825 | — | — | — | € 4.33 |
| 01/28/2011 | BSA | 10,039 | 7,529 | — | — | € 5.13 |
| 06/24/2011 | BSA/BSPCE | 32,000 | — | 7,666 | 114,990 | € 5.13 |
| 11/22/2011 | BSA/BSPCE | 11,377 | — | — | — | € 5.13 |
| 01/17/2012 | BSA | 89,835 | — | — | — | € 5.13 |
| 04/02/2012 | AGA | 669,796 | 1,860 | — | — | € — |
| 07/25/2012 | AGA | 134,081 | — | — | — | € — |
| 09/25/2012 | BSA | 30,000 | — | 5,000 | 5,000 | € 8.59 |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 11/28/2012 | AGA | 35,360 | — | — | — | € — |
| 07/25/2013 | BSA | 73,000 | — | 7,000 | 7,000 | € 8.10 |
| 09/12/2013 | AGA | 501,500 | 113,333 | — | — | € — |
| 09/18/2013 | SO | 518,000 | 47,000 | 203,000 | 203,000 | € 7.57 |
| 06/03/2014 | BSA | 10,000 | — | — | — | € 18.79 |
| 06/03/2014 | AGA | 186,000 | 30,000 | — | — | € — |
| 06/03/2014 | SO | 75,000 | — | 40,000 | 40,000 | € 19.01 |
| 03/24/2015 | BSA | 10,000 | — | 10,000 | 10,000 | € 43.00 |
| 06/23/2015 | SO | 120,000 | — | 120,000 | 120,000 | € 48.90 |
| 09/30/2015 | AGA | 708,500 | 23,000 | — | — | € — |
| 11/19/2015 | SO | 195,000 | 25,000 | 170,000 | 170,000 | € 66.06 |
| 11/19/2015 | BSA | 22,500 | 7,500 | 15,000 | 15,000 | € 66.06 |
| 12/15/2015 | AGA | 42,000 | 9,000 | — | — | € — |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 12/15/2015 | BSA | 90,000 | 16,500 | 73,500 | 73,500 | € 64.14 |
| 01/04/2016 | SO | 75,000 | — | 75,000 | 75,000 | € 65.68 |
| 04/06/2016 | AGA | 63,750 | 6,250 | — | — | € — |
| 04/21/2016 | SO | 33,000 | 11,000 | 22,000 | 22,000 | € 62.82 |
| 05/02/2016 | SO | 22,000 | 22,000 | — | — | € 59.04 |
| 06/21/2016 | SO | 110,000 | 21,300 | 87,500 | 87,500 | € 53.96 |
| 06/21/2016 | BSA | 20,000 | — | 20,000 | 20,000 | € 52.97 |
| 06/21/2016 | AGA | 208,000 | — | — | — | € — |
| 08/01/2016 | SO | 10,000 | — | 10,000 | 10,000 | € 62.24 |
| 09/15/2016 | SO | 9,300 | — | 9,300 | 9,300 | € 62.80 |
| 10/17/2016 | SO | 16,500 | 7,200 | 9,300 | 9,300 | € 64.39 |
| 10/27/2016 | AGA | 15,000 | — | — | — | € — |
| 11/15/2016 | SO | 8,300 | — | 8,300 | 8,300 | € 68.33 |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 12/09/2016 | SO | 74,960 | 22,965 | 51,995 | 51,995 | € 69.75 |
| 12/09/2016 | AGA | 23,600 | 3,800 | — | — | € — |
| 12/09/2016 | BSA | 59,000 | 24,992 | 34,008 | 34,008 | € 69.75 |
| 12/15/2016 | SO | 1,100 | — | 1,100 | 1,100 | € 69.35 |
| 01/16/2017 | SO | 19,100 | — | 19,100 | 19,100 | € 66.11 |
| 03/14/2017 | AGA | 22,500 | 5,500 | 17,000 | 17,000 | € — |
| 03/17/2017 | SO | 7,200 | — | 7,200 | 7,200 | € 66.25 |
| 04/18/2017 | SO | 16,500 | 9,300 | 7,200 | 7,200 | € 60.77 |
| 04/20/2017 | AGA | 24,000 | — | 24,000 | 24,000 | € — |
| 06/15/2017 | SO | 126,000 | 35,000 | 91,000 | 91,000 | € 59.05 |
| 06/15/2017 | SO | 111,600 | — | 111,600 | 111,600 | € 60.54 |
| 06/15/2017 | BSA | 9,000 | — | 9,000 | 9,000 | € 59.05 |
| 07/17/2017 | SO | 30,900 | 23,700 | 7,200 | 7,200 | € 71.61 |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 09/15/2017 | SO | 52,600 | 7,200 | 45,400 | 45,400 | € 74.22 |
| 12/05/2017 | SO | 625,200 | 85,125 | 540,075 | 540,075 | € 39.00 |
| 12/15/2017 | SO | 8,300 | — | 8,300 | 8,300 | € 38.18 |
| 01/15/2018 | SO | 15,500 | 7,200 | 8,300 | 8,300 | € 43.60 |
| 04/16/2018 | SO | 16,500 | — | 16,500 | 16,500 | € 38.64 |
| 05/16/2018 | SO | 16,500 | — | 16,500 | 16,500 | € 40.84 |
| 06/15/2018 | SO | 23,600 | — | 23,600 | 23,600 | € 38.92 |
| 06/22/2018 | SO | 50,000 | — | 50,000 | 50,000 | € 37.22 |
| 06/22/2018 | AGA | 486,153 | 21,125 | 465,028 | 465,028 | € — |
| 07/02/2018 | BSA | 44,000 | — | 44,000 | 44,000 | € 37.24 |
| 07/16/2018 | SO | 28,800 | — | 28,800 | 28,800 | € 33.81 |
| 08/15/2018 | SO | 33,500 | — | 33,500 | 33,500 | € 32.90 |
| 09/06/2018 | SO | 65,000 | — | 65,000 | 65,000 | € 36.96 |

| Date | Type | Number of warrants issued as of 12/31/2018 | Number of warrants null and void as of 12/31/2018 | Number of warrants null and outstanding as of 12/31/2018 | Maximum number of shares to be issued | Strike price per share |
|---|---|---|---|---|---|---|
| 06/09/2018 | AGA | 450 | — | 450 | 450 | € — |
| 09/17/2018 | SO | 80,900 | — | 80,900 | 80,900 | € 40.94 |
| 10/15/2018 | SO | 76,700 | — | 76,700 | 76,700 | € 37.28 |
| 11/01/2018 | AGA | 57,000 | 10,500 | 46,500 | 46,500 | € — |
| 11/15/2018 | SO | 26,000 | — | 26,000 | 26,000 | € 32.57 |
| 11/29/2018 | SO | 350,000 | — | 350,000 | 350,000 | € 30.02 |
| 12/12/2018 | SO | 34,000 | — | 34,000 | 34,000 | € 27.96 |
| 12/12/2018 | AGA | 19,250 | — | 19,250 | 19,250 | € — |
| 12/17/2018 | SO | 7,200 | — | 7,200 | 7,200 | € 26.76 |
| **Total** | | **6,819,669** | **605,451** | **3,258,972** | **3,366,296** | |

The totals presented above do not include the warrants cancelled prior to December 31, 2009.

As part of the initial public offering on Euronext, the nominal value of the shares underwent a fifteen-for-one share split following the decision of the Combined General Meeting of December 9, 2011.

The impact of the share-based payments on the net income (or loss) is presented in Note 17.

**Note 11: Financial and Other Non-Current Liabilities**

***11.1 Conditional Advances***

The conditional advances from public institutions are subject to contracts with OSEO and COFACE.

As of December 31, 2018, the Company had two advance contracts with OSEO Innovation. These advances are 100% repayable at their nominal value in the event of technical and/or commercial success and do not bear interest.

The Company also benefited from a third grant from BpiFrance Financement in November 2014.

The agreement with COFACE terminated on December 31, 2016, generating an exceptional income of €146 thousand corresponding to allowances which could not be reimbursed along with Company takings, and which therefore remain acquitted to the Company.

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

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

| | 3rd OSEO contract | 4th OSEO contract | BPI advance | COFACE | Total |
|---|---|---|---|---|---|
| **Balance sheet debt at start of period 01/01/2016** | **318** | **1,669** | **2,666** | **156** | **4,809** |
| Receipts | — | — | — | — | — |
| Repayments | (128) | — | — | (147) | (275) |
| Other transactions | 2 | 16 | 85 | (9) | 95 |
| **Balance sheet debt as at 12/31/2016** | **192** | **1,684** | **2,751** | **—** | **4,628** |
| Of which—Non-current portion | | | | | 4,049 |
| Of which—Current portion | | | | | 578 |
| Stated interest rate | **No** | **2.05%** | **No** | **No** | |
| Discount rate | **0.4%-1.9%** | **1.5%-1.8%** | **3.20%** | **4.25%** | |
| Maturity (in years) | **0-3** | **7-9** | **2-7** | **0** | |

| | 3rd OSEO contract | 4th OSEO contract | BPI advance | Total |
|---|---|---|---|---|
| **Balance sheet debt at start of period 01/01/2017** | **192** | **1,684** | **2,751** | **4,627** |
| Receipts | — | — | — | — |
| Repayments | (128) | — | (450) | (578) |
| Other transactions | 1 | 16 | 84 | 101 |
| **Balance sheet debt as at 12/31/2017** | **64** | **1,700** | **2,386** | **4,150** |
| Of which—Non-current portion | | | | 1,825 |
| Of which—Current portion | | | | 2,325 |
| Stated interest rate | **No** | **2.05%** | **No** | |
| Discount rate | **0.4%-1.9%** | **1.5%-1.8%** | **3.2%** | |
| Maturity (in years) | **0-3** | **7-9** | **2-7** | |

| | 3rd OSEO contract | 4th OSEO contract | BPI advance | Total |
|---|---|---|---|---|
| **Balance sheet debt at start of period 01/01/2018** | **64** | **1,700** | **2,386** | **4,150** |
| Receipts | — | — | — | — |
| Repayments | (64) | (1,136) | (600) | (1,800) |
| Other transactions | — | 60 | 69 | 129 |
| **Balance sheet debt as at 12/31/2018** | **—** | **624** | **1,854** | **2,479** |
| Of which—Non-current portion | | | | 1,278 |
| Of which—Current portion | | | | 1,201 |
| Stated interest rate | **No** | **2.05%** | **No** | |
| Discount rate | **0.4%-1.9%** | **1.5%-1.8%** | **3.2%** | |
| Maturity (in years) | **0-3** | **7-9** | **2-7** | |

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

*Third OSEO Advance*

In 2011, the Company was notified by OSEO Innovation of a new grant in the form of a conditional advance of up to €640,000 to finance the development of its program to treat the allergy to proteins in cow's milk.

The amount of the assistance was paid as follows:

- €256,000 after the contract was signed (payment was received in 2011);
- €256,000 from June 30, 2012 upon a call for funds (payment was received in 2013);
- the balance of €128,000 after confirmation of the end of the program notified on December 31, 2013 (payment was received in 2014).

In the event of technical or commercial success of the program, the repayment schedule will be the following:

- Four quarterly repayments of €64,000 each starting no later than September 30, 2014;
- Twelve quarterly repayments of €32,000 each starting no later than September 30, 2015.

A fixed sum of €256,000 has been repaid in four quarterly installments of €64,000 beginning on September 30, 2014.

The agreement with OSEO terminated on June 30, 2018.

*Fourth OSEO Advance*

In 2013, OSEO has provided assistance in the form of conditional advances for €3,206,162 to the Company as part of a collaborative research and clinical development in mite allergy in young children. ImmunaVia, the program, will be funded according to the following schedule, subject to the progress of the program:

- €903,500 paid in April 2013;
- €903,500 in October 2014 (funds which were to be paid in October 2014 were finally received on January 22, 2015 for an amount of €864,989);
- €918,000 in October 2015 (not received);

- €481,162 in April 2018 (not received).

The funds that the Company actually received amounts to €1,768,489.

Such conditional advance bears interest at an annual rate of 2.05%. In case of technical or commercial success of the project, the repayment schedule, for a total amount of €3,750,000 (including interest), is as follows:

- €400,000 on or before June 30, 2021;
- €800,000 on or before June 30, 2022;
- €1,100,000 no later than June 30, 2023;
- €1,450,000 no later than June 30, 2024.

Following the defection of a sponsor, the Immunavia project was interrupted in September 2017. The Company was required to reimburse the remaining amounts of conditional advances. The reimbursment been rescheduled in 13 monthly repayments, commencing on May 31, 2018, through May 31, 2019.

*BpiFrance Financement Interest-Free Loan*

In 2014, BpiFrance Financement granted an interest-free Innovation loan of €3,000,000 to DBV Technologies to help financing the pharmaceutical development of Viaskin® Milk. This amount was received in a single disbursement on November 27, 2014.

The planned repayment is scheduled in 20 quarterly repayments of €150,000 each, starting on June 30, 2017.

*COFACE Advance*

On September 6, 2007, DBV Technologies signed a prospecting insurance contract with Compagnie Française d'Assurance pour le Commerce Extérieur ("COFACE") in order to promote its Diallertest product internationally. Under the terms of that contract, the Company received conditional advances of up to €147 thousands. DBV Technologies must repay these advances in amounts of up to 7% of its revenue from the export sales of its Diallertest product, until April 30, 2017.

The agreement with COFACE was terminated on December 31, 2016, and has generated an income of €146 thousand corresponding to the remaining amount of the advance, which will not be refunded.

***11.2 Other non-current liabilities***

Other non-current liabilities mainly include non-current part of deferred revenue from the collaboration agreement the Company entered into with Nestlé Health Science, which amounted to €6.5 million as of December 31, 2018. More marginally, non-current liabilities also included the non-current part of deferred revenue from free-rent amounts deferred over Montrouge premises' lease term and the non-current part of the accrual for employers' contribution on free share plans.

*11.3 Due Dates of the Financial Liabilities and other non-current liabilities*

Due dates of the financial liabilities recognized as of December 31, 2016:

| | Gross amount | Less than One year | One to Five Years | More than Five Years |
|---|---|---|---|---|
| | | (Amounts in thousands of Euros) | | |
| Non-current conditional advances | 4,049 | — | 2,531 | 1,518 |
| Non-current financial rent debts | — | — | — | — |
| Other non-current liabilities | 10,746 | — | 10,370 | 377 |
| Current conditional advances | 578 | 578 | — | — |
| Current financial rent debts | 12 | 12 | — | — |
| Other current liabilities | 14,692 | 14,692 | — | — |
| Supplier accounts payable and related payables | 13,720 | 13,720 | — | — |
| **Total financial liabilities** | **43,798** | **29,003** | **12,900** | **1,895** |

Due dates of the financial liabilities recognized as of December 31, 2017:

| | Gross amount | Less than One year | One to Five Years | More than Five Years |
|---|---|---|---|---|
| | | (Amounts in thousands of Euros) | | |
| Non-current conditional advances | 1,825 | — | 1,825 | — |
| Non-current financial rent debts | — | — | — | — |
| Other non-current liabilities | 8,869 | — | 8,421 | 448 |
| Current conditional advances | 2,325 | 2,325 | — | — |
| Current financial rent debts | — | — | — | — |
| Other current liabilities | 15,751 | 15,751 | — | — |
| Supplier accounts payable and related payables | 16,941 | 16,941 | — | — |
| **Total financial, current and non-current liabilities** | **45,711** | **35,017** | **10,246** | **448** |

Due dates of the financial liabilities recognized as of December 31, 2018:

| | Gross amount | Less than One year | One to Five Years | More than Five Years |
|---|---|---|---|---|
| | | (Amounts in thousands of Euros) | | |
| Non-current conditional advances | 1,278 | — | 1,278 | — |
| Non-current financial rent debts | — | — | — | — |
| Other non-current liabilities | 4,105 | — | 3,991 | 114 |
| Current conditional advances | 1,201 | 1,201 | — | — |
| Current financial rent debts | — | — | — | — |
| Other current liabilities | 12,506 | 12,506 | — | — |
| Supplier accounts payable and related payables | 28,567 | 28,567 | — | — |
| **Total financial, current and non-current liabilities** | **47,657** | **42,273** | **5,269** | **114** |

As detailed in Note 13, other current liabilities mainly include social security and current part of deferred revenues from the collaboration agreement with Nestlé Health Science as well as subsidies and conditional advances.

**Note 12: Non-Current Provisions**

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| Pension retirement obligations | 853 | 1,260 | 1,536 |
| **Total** | **853** | **1,260** | **1,536** |

***Commitments for Compensation Payable to Employees Upon Their Retirement***

| | Amounts in thousands of Euros |
|---|---|
| **As of January 1, 2016** | **(490)** |
| Costs of services rendered (operating expense) | (104) |
| Interest expense (financial expense) | (10) |
| Benefit paid | — |
| Actuarial losses | (249) |
| **As of December 31, 2016** | **(853)** |
| Costs of services rendered (operating expense) | (219) |
| Interest expense (financial expense) | (11) |
| Benefit paid | — |
| Actuarial losses | (177) |
| **As of December 31, 2017** | **(1,260)** |
| Costs of services rendered (operating expense) | (412) |
| Interest expense (financial expense) | (24) |
| Benefit paid | 141 |
| Actuarial losses | 19 |
| **As of December 31, 2018** | **(1,536)** |

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

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| % social security contributions | 50.0% | 50.0% | 50.0% |
| Salary increases | 2.0% | 2.0% | 2.0% |
| Discount rate | 1.31% | 1.30% | 1.57% |

Assumptions for the years ended December 31, 2016:

- Retirement age: 65 years old;
- Terms of retirement: voluntary retirement;
- Life table: INSEE 2010;

- Collective agreement: Convention Collective Nationale de l'Industrie Pharmaceutique (National Collective Agreement in the Pharmaceutical Industry);
- Turn-over of the personnel declining with age.

Assumptions for the years ended December 31, 2017 and 2018:

- Retirement age: 65 years old;
- Terms of retirement: voluntary retirement;
- Life table: TGH05-TGF05;
- Collective agreement: Convention Collective Nationale de l'Industrie Pharmaceutique (National Collective Agreement in the Pharmaceutical Industry);
- Turn-over of the personnel declining with age.

The discount rates come from the corporate AA zero coupon yield curve.

No employee has retired during the last three fiscal years presented.

**Note 13: Supplier Accounts Receivable and Other Current Liabilities**

***13.1 Supplier Accounts Payable and Related Payables***

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

***13.2 Other Current Liabilities***

| | 2016 | 2017 | 2018 |
|---|---|---|---|
| | (Amounts in thousands of Euros) | | |
| Social security | 10,794 | 12,094 | 6,343 |
| Tax liabilities | 504 | 428 | 448 |
| Other debts | 146 | 440 | 1,354 |
| Deferred revenues | 3,248 | 2,789 | 4,360 |
| **Total** | **14,692** | **15,751** | **12,506** |

The other liabilities include the short-term debts to employees, as well as social welfare and tax agencies. Deferred revenues include subsidies, conditional advances and current part of deferred revenues from the collaboration agreement with Nestlé Health Science.

**Note 14: Financial Instruments Recognized in the Consolidated Statements of Financial Position and Related Effect on the Consolidated Statements of (Loss)**

| 2016 | Book value in the Consolidated Statements of Financial Position | Fair value through Consolidated Statements of (Loss) (1) | Loans and receivables (2) | Debt At amortized cost (3) | Fair value |
|---|---|---|---|---|---|
| **Financial assets** | | | | | |
| Long-term financial assets | 2,745 | 1,310 | 1,435 | — | 2,745 |
| Customer accounts receivables and related receivables | 1,250 | — | 1,250 | — | 1,250 |
| Other current financial assets | 516 | — | 516 | — | 516 |
| Cash and cash equivalents | 256,473 | 256,473 | — | — | 256,473 |
| **Total financial assets** | **260,985** | **257,783** | **3,202** | **—** | **260,985** |
| **Financial liabilities** | | | | | |
| Long-term conditional advances | 4,049 | — | — | 4,049 | 4,049 |
| Long term financial rent debt | — | — | — | — | — |
| Other long-term liabilities | 10,746 | — | — | 10,746 | 10,746 |
| Short-term conditional advances | 578 | — | — | 578 | 578 |
| Short term financial rent debt | 12 | — | — | 12 | 12 |
| Other short-term liabilities | 14,692 | — | — | 14,692 | 14,692 |
| Account payable and other liabilities | 13,720 | — | — | 13,720 | 13,720 |
| **Total financial liabilities** | **43,798** | **—** | **—** | **43,798** | **43,798** |

| 2017 | Book value in the Consolidated Statements of Financial Position | Fair value through Consolidated Statements of (Loss) (1) | Loans and receivables (2) | Debt At amortized cost (3) | Fair value |
|---|---|---|---|---|---|
| **Financial assets** | | | | | |
| Long-term financial assets | 3,012 | 1,333 | 1,679 | — | 3,012 |
| Customer accounts receivables and related receivables | 1,265 | — | 1,265 | — | 1,265 |
| Other current financial assets | 378 | — | 378 | — | 378 |
| Cash and cash equivalents | 137,880 | 137,880 | — | — | 137,880 |
| **Total financial assets** | **142,534** | **139,213** | **3,321** | **—** | **142,534** |
| **Financial liabilities** | | | | | |
| Long-term conditional advances | 1,825 | — | — | 1,825 | 1,825 |
| Long term financial rent debt | — | — | — | — | — |
| Other long-term liabilities | 8,869 | — | — | 8,869 | 8,869 |
| Short-term conditional advances | 2,325 | — | — | 2,325 | 2,325 |
| Short term financial rent debt | — | — | — | — | — |
| Other short-term liabilities | 15,751 | — | — | 15,751 | 15,751 |
| Account payable and other liabilities | 16,941 | — | — | 16,941 | 16,941 |
| **Total financial liabilities** | **45,711** | **—** | **—** | **45,711** | **45,711** |

| 2018 | Book value in the Consolidated Statements of Financial Position | Fair value through Consolidated Statements of (Loss) (1) | Financial assets at amortized cost | Non-derivative financial liabilities (3) | Fair value (2) |
|---|---|---|---|---|---|
| **Financial assets** | | | | | |
| Long-term financial assets | 6,033 | 432 | 5,601 | — | 6,033 |
| Customer accounts receivables and related receivables | — | — | — | — | — |
| Other current financial assets | 912 | — | 912 | — | 912 |
| Cash and cash equivalents | 122,770 | — | 122,770 | — | 122,770 |
| **Total financial assets** | **129,715** | **432** | **129,283** | **—** | **129,715** |
| **Financial liabilities** | | | | | |
| Long-term conditional advances | 1,278 | — | — | 1,278 | 1,278 |
| Long term financial rent debt | — | — | — | — | — |
| Other long-term liabilities | 4,105 | — | — | 4,105 | 4,105 |
| Short-term conditional advances | 1,201 | — | — | 1,201 | 1,201 |
| Short term financial rent debt | — | — | — | — | — |
| Other short-term liabilities | 12,506 | — | — | 12,506 | 12,506 |
| Account payable and other liabilities | 28,567 | — | — | 28,567 | 28,567 |
| **Total financial liabilities** | **47,656** | **—** | **—** | **47,656** | **47,656** |

(1) The fair value of financial assets as fair value through Consolidated Statements of (Loss) is determined based on Level 1 fair value measurements and corresponds to the market value of the assets.

(2) The fair value of "financial assets at amortized cost" as per IFRS 9 or "loans and receivables" as per IAS 39 corresponds to the value reported in the Consolidated Statements of Financial Position.

(3) The book amount of "Non-derivative financial liabilities" as per IFRS 9 or "financial liabilities" as per IAS 39 measured at amortized cost was deemed to be a reasonable estimation of fair value.

**Note 15: Operating Income**

The operating income is broken down in the following manner:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Revenues | — | — | — |
| Research tax credit | 7,228 | 9,330 | 11,034 |
| Subsidies | 303 | 271 | 152 |
| Other operating income | 1,554 | 2,308 | 3,351 |
| **Total** | **9,084** | **11,909** | **14,537** |

The Company recognized as other income a portion of the upfront fee and milestones agreed under the contract with Nestlé which are deferred over the performance obligation. As of December 31, 2018, the end of the service obligation period over which the revenue from Nestlé will be deferred is expected by 2022.

**Note 16: Operating Expenses**

The research and development expenses are broken down as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| **Research and development expenses** | (Amounts in thousands of Euros) | | |
| Personnel expenses | 32,777 | 37,112 | 37,912 |
| Sub-contracting, collaboration, and consultants | 34,413 | 54,397 | 52,927 |
| Small equipments and other supplies | 3,909 | 4,110 | 4,771 |
| Rental | 1,903 | 2,018 | 2,703 |
| Conferences, travel expenses | 2,387 | 2,807 | 2,591 |
| Depreciation and amortization | 1,141 | 2,424 | 2,492 |
| Others | 2,298 | 2,364 | 3,776 |
| **Total research and development expenses** | **78,828** | **105,232** | **107,171** |

The sales and marketing expenses are broken down as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| **Sales and marketing expenses** | (Amounts in thousands of Euros) | | |
| Personnel expenses | 4,954 | 6,976 | 12,553 |
| Fees | 4,447 | 2,480 | 5,148 |
| Communication and travel expenses | 1,393 | 5,984 | 14,021 |
| Others | 487 | 384 | 446 |
| **Total sales and marketing expenses** | **11,282** | **15,824** | **32,169** |

By nature, the breakdown of general and administrative expenses is as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| **General and administrative expenses** | (Amounts in thousands of Euros) | | |
| Personnel expenses | 22,613 | 19,742 | 19,101 |
| Fees | 7,701 | 10,347 | 12,718 |
| Rental | 501 | 584 | 911 |
| Insurance policies | 1,853 | 1,367 | 1,930 |
| Communication and travel expenses | 1,136 | 1,599 | 1,576 |
| Depreciation and amortization | 181 | 422 | 1,720 |
| Others | 1,020 | 1,776 | 3,442 |
| **Total general and administrative expenses** | **35,005** | **35,837** | **41,399** |

***Personnel Expenses***

The Company had 315 employees at December 31, 2018, in comparison with 242 employees at December 31, 2017 and 164 employees at December 31, 2016.

The personnel expenses are broken down as follows:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Wages and salaries | 14,651 | 22,451 | 31,684 |
| Social security contributions | 3,903 | 7,157 | 8,858 |
| Expenses for pension commitments | 982 | 1,583 | 2,095 |
| Employer contribution to bonus shares | 6,456 | 1,857 | 1,026 |
| Share-based payments | 34,353 | 30,781 | 25,904 |
| **Total** | **60,345** | **63,830** | **69,567** |

The increase in personnel charges is mainly due to the increase in the Company's headcount. This increase was partially offset by the decrease of the share-based payments expense and employer contribution to free shares.

**Note 17: Share-Based Payments**

The Board of Directors has been authorized by the general meeting of the shareholders to grant employee warrants (*Bons de Souscription de Parts de Créateur d'Entreprise* or "BSPCE") and (Bons de Souscription d'Actions or "BSA"), Free shares and to implement share options plans as follows:

- With the authorization of the General Meeting of Shareholders on January 21, 2009, the Board of Directors issued 2,296 BCEX ("BCEX");
- With the authorization of the General Meeting of Shareholders on June 14, 2007, December 16, 2010 and December 9, 2011, the board of Directors issued 194,552 BSA ("BSA");
- With the authorization of the General Meeting of Shareholders on January 21, 2009, the Board of Directors issued 10,716 BSA ("BSA2");
- With the authorization of the General Meeting of Shareholders on January 21, 2009, the Board of Directors issued 5,358 BCE ("BCE4");
- With the authorization of the General Meeting of Shareholders on December 16, 2010, the Board of Directors issued 19,377 BSA ("BSA2010");
- With the authorization of the General Meeting of Shareholders on January 21, 2009, the Board of Directors issued 2,131 BSA ("BSAX");
- With the authorization of the General Meeting of Shareholders on December 16, 2010, the Board of Directors issued 34,039 BSPCE ("BSPCE2010");
- With the authorization of the General Meeting of Shareholders on December 9, 2011, the Board of Directors issued 518,000 options ("OPTIONS 2013");
- With the authorization of the General Meeting of Shareholders on December 9, 2011, the Board of Directors issued 1,340,737 Free shares ("Free shares");
- With the authorization of the General Meeting of Shareholders on June 4, 2013, the Board of Directors issued 73,000 BSA;
- With the authorization of the General Meeting of Shareholders on June 3, 2014, the Board of Directors issued 20,000 BSA;
- With the authorization of the General Meeting of Shareholders on June 3, 2014, the Board of Directors issued 918,960 options;
- With the authorization of the General Meeting of Shareholders on June 3, 2014, the Board of Directors issued 186,000 free shares;
- With the authorization of the General Meeting of Shareholders on June 23, 2015, the Board of Directors issued 88,500 BSA;
- With the authorization of the General Meeting of Shareholders on September 21, 2015, the Board of Directors granted 1,107,350 Free shares which 241,844 have been issued as of December 31, 2017;
- With the authorization of the General Meeting of Shareholders on June 21, 2016, the Board of Directors issued 54,008 BSA;
- With the authorization of the General Meeting of Shareholders on June 15, 2017, the Board of Directors issued 9,000 BSA;
- With the authorization of the General Meeting of Shareholders on June 15, 2017, the Board of Directors issued 900,700 options which 72,100 have been issued as of first half 2018;
- With the authorization of the General Meeting of Shareholders on June 22, 2018, the Board of Directors issued 562,853 free shares;
- With the authorization of the General Meeting of Shareholders on June 2, 2018, the Board of Directors issued 752,100 options;

**17.1 BSA**

***Date of Grant 12/07/2007***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BSA on the first anniversary of the date of grant;
- up to one fourth (1/4) of the BSA on the second anniversary of the date of grant;
- up to one fourth (1/4) of the BSA on the third anniversary of the date of grant;
- up to one fourth (1/4) of the BSA on the fourth anniversary of the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 01/17/2012***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 89,835 BSA (all the BSA) on January 17, 2016; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 09/25/2012***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 30,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 07/25/2013***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 73,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 06/03/2014***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 10,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 24/03/2015***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 10,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 19/11/2015***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 15,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 15/12/2015***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 73,500 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 06/21/2016***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 20,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 12/09/2016***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 34,008 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 06/15/2017***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 9,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Date of Grant 05/02/2018***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 44,000 BSA (all the BSA) on the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Details of BSA***

| **Date of grant (Board of Directors)** | **12/07/2007** | **12/07/2007** | **12/07/2007** | **12/07/2007** | **01/17/2012** | **01/17/2012** | **01/17/2012** | **01/17/2012** |
|---|---|---|---|---|---|---|---|---|
| Vesting period (years) | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Plan expiration date | 12/08/2017 | 12/08/2017 | 12/08/2017 | 12/08/2017 | 01/17/2022 | 01/17/2022 | 01/17/2022 | 01/17/2022 |
| Number of BSA granted | 431 | 431 | 428 | 427 | 22,459 | 22,459 | 22,459 | 22,458 |
| Share entitlement per BSA(1) | 15 | 15 | 15 | 15 | 1 | 1 | 1 | 1 |
| Exercise price | 65 | 65 | 65 | 65 | 5.13 | 5.13 | 5.13 | 5.13 |
| **Valuation method used** | **Black—Scholes** | | | | | | | |
| Grant date share fair value | 65 | 65 | 65 | 65 | 5.13 | 5.13 | 5.13 | 5.13 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% | 40% | 40% | 40% |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Average life of BSA | 4.5 | 5.0 | 5.5 | 6.0 | 5.5 | 6.0 | 6.5 | 7.0 |
| Discount rate(2) | 4.06% | 4.09% | 4.09% | 4.10% | 2.33% | 2.33% | 2.61% | 2.61% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA | NA |
| Fair value per BSA | 22.18 | 23.62 | 24.95 | 26.22 | 2.05 | 2.14 | 2.26 | 2.34 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BSA warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BSA plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSA.

| **Date of grant (Board of Directors)** | **09/25/2012** | **09/25/2012** | **09/25/2012** | **09/25/2012** | **07/25/2013** | **06/03/2014** |
|---|---|---|---|---|---|---|
| Vesting period (years) | 1 | 2 | 3 | 4 | 0 | 0 |
| Plan expiration date | 09/25/2022 | 09/25/2022 | 09/25/2022 | 09/25/2022 | 07/25/2023 | 06/03/2024 |
| Number of BSA granted | 7,500 | 7,500 | 7,500 | 7,500 | 73,000 | 10,000 |
| Share entitlement per BSA | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 8.59 | 8.59 | 8.59 | 8.59 | 8.1 | 18.79 |
| **Valuation method used** | | | **Black—Scholes** | | | |
| Grant date share fair value | 8.4 | 8.4 | 8.4 | 8.4 | 8.15 | 19.01 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% | 40% |
| Average life of BSA | 5.5 | 6.0 | 6.5 | 7.0 | 5.0 | 5.0 |
| Discount rate(1) | 1.21% | 1.21% | 1.53% | 1.53% | 1.16% | 0.71% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA |
| Fair value per BSA | 2.29 | 2.43 | 2.61 | 2.74 | 2.18 | 4.98 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSA.

| **Date of grant (Board of Directors)** | **03/24/2015** | **11/19/2015** | **12/15/2015** | **06/21/2016** |
|---|---|---|---|---|
| Vesting period (years) | | | | |
| Plan expiration date | 03/24/2025 | 11/19/2025 | 12/15/2015 | 06/21/2016 |
| Number of BSA granted | 10,000 | 15,000 | 90,000[(1)] | 20,000 |
| Share entitlement per BSA | 1 | 1 | 1 | 1 |
| Exercise price | 43.00 | 66.06 | 64.14 | 52.97 |
| **Valuation method used** | | **Black—Scholes** | | |
| Grant date share fair value | 43 | 66.06 | 42.61 | 61.25 |
| Expected volatility | 36% | 50.91% | 51% | 47% |
| Average life of BSA | 5.0 | 5.0 | 5.0 | 5.0 |

| | | | | |
|---|---|---|---|---|
| Discount rate(1) | 0.68% | 0.81% | -0.09% | -0.41% |
| Expected dividends | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA |
| Fair value per BSA | 9.90 | 22.60 | 7.28 | 21.59 |

| Date of grant (Board of Directors) | 12/09/2016 | 06/15/2017 | 05/02/2018 |
|---|---|---|---|
| Vesting period (years) | 0 | 0 | 0 |
| Plan expiration date | 12/09/2026 | 06/15/2027 | 05/02/2028 |
| Number of BSA granted | 59,000 | 9,000 | 44,000 |
| Share entitlement per BSA | 1 | 1 | 1 |
| Exercise price | 69.75 | 59.05 | 37.24 |
| **Valuation method used** | | **Black—Scholes** | |
| Grant date share fair value | 63.18 | 73.32 | 37.74 |
| Expected volatility | 40% | 39% | 50% |
| Average life of BSA | 5.0 | 5.0 | 5.0 |
| Discount rate(1) | -0.04% | -0.12% | -0.15% |
| Expected dividends | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA |
| Fair value per BSA | 12.94 | 24.02 | 9.02 |

Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSA.

***Change in Number of BSA Outstanding***

| | Year ended December 31, | | |
|---|---|---|---|
| Number of BSA | 2016 | 2017 | 2018 |
| Balance at beginning of period | 143,694 | 147,359 | 181,008 |
| Granted during the period | 93,500 | 68,000 | 44,000 |
| Forfeited during the period | — | 24,902 | — |
| Exercised during the period | 89,835 | 9,359 | 7,500 |
| Expired during the period | — | — | — |
| **Balance at end of period** | **147,359** | **181,008** | **217,508** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| **Number of BSA** | **Outstanding** | **Outstanding** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** |
| BSA2010 with exercise price of €65 | 859 | 859 | — | — | — | — |
| BSA2010 with exercise price of €5.13 | — | — | — | — | — | — |
| BSA2010 with exercise price of €8.59 | 10,000 | 10,000 | 7,500 | 7,500 | 5,000 | 5,000 |
| BSA2010 with exercise price of €8.10 | 13,000 | 13,000 | 9,500 | 9,500 | 7,000 | 7,000 |
| BSA2010 with exercise price of €18.79 | 5,000 | 5,000 | 2,500 | 2,500 | — | — |
| BSA with exercise price of €43.00 | 10,000 | 10,000 | 10,000 | 10,000 | 10,000 | 10,000 |
| BSA with exercise price of €66.06 | 15,000 | 15,000 | 15,000 | 15,000 | 15,000 | 15,000 |
| BSA with exercise price of €64.14 | 73,500 | 73,500 | 73,500 | 73,500 | 73,500 | 73,500 |
| BSA with exercise price of €52.97 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 | 20,000 |
| BSA with exercise price of €69.75 | — | — | 34,008 | 34,008 | 34,008 | 34,008 |
| BSA with exercise price of €59.05 | — | — | 9,000 | 9,000 | 9,000 | 9,000 |
| BSA with exercise price of €37.24 | — | — | — | — | 44,000 | 44,000 |
| **Total** | **147,359** | **147,359** | **181,008** | **181,008** | **217,508** | **217,508** |

**17.4 BCE 4**

The BCE4 may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 2,411 BCE4 on the date of grant;
- up to 1,340 BCE4 on the first anniversary of the date of grant;
- up to 536 BCE4 on the second anniversary of the date of grant;
- up to 536 BCE4 on the third anniversary of the date of grant;
- up to 535 BSA on the fourth anniversary of the date of grant; and
- at the latest within ten (10) years from the date of grant.

By a decision by the Board of Directors meeting held on November 22, 2011, the BCE4 warrants became exercisable beginning on the date of the first quotation of the shares of the Company on the Euronext regulated market in Paris.

***Details of BCE4***

| **Date of grant (Board of Directors)** | **01/21/2009** | **01/21/2009** | **01/21/2009** | **01/21/2009** | **01/21/2009** |
|---|---|---|---|---|---|
| Vesting period (years) | 0 | 1 | 2 | 3 | 4 |
| Plan expiration date | 01/20/2019 | 01/20/2019 | 01/20/2019 | 01/20/2019 | 01/20/2019 |
| Number of BCE4 granted | 2,411 | 1,340 | 536 | 536 | 535 |
| Share entitlement per BCE4(1) | 15 | 15 | 15 | 15 | 15 |
| Exercise price | 65 | 65 | 65 | 65 | 65 |
| **Valuation method used** | | | **Black—Scholes** | | |
| Grant date share fair value | 70 | 70 | 70 | 70 | 70 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% |
| Average life of BCE4 | 5.0 | 5.5 | 6.0 | 6.5 | 7.0 |
| Discount rate(2) | 2.71% | 2.71% | 2.98% | 2.98% | 3.11% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA |
| Fair value per BCE4 | 29.06 | 30.33 | 31.90 | 33.06 | 34.35 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BCE4 warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BCE4 plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BCE4.

***Change in Number of BCE4 Outstanding***

| | Year ended December 31, | | |
|---|---|---|---|
| **Number of BCE4** | **2016** | **2017** | **2018** |
| Balance at beginning of period | 2,691 | 2,691 | — |
| Granted during the period | — | — | — |
| Forfeited during the period | — | — | — |
| Exercised during the period | — | 2,691 | — |
| Expired during the period | — | — | — |
| **Balance at end of period** | **2,691** | **—** | **—** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| **Number of BCE4** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** |
| BCE4 with exercise price of €65 | 2,691 | 2,691 | — | — | — | — |
| **Total** | **2,691** | **2,691** | — | — | — | — |

**17.5 BSA2010**

***Date of Grant 01/28/2011***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 2,510 BSA on the 12/23/2011;
- up to 2,510 BSA on the 12/23/2012;
- up to 2,510 BSA on the 12/23/2013;
- up to 2,509 BSA on the 12/23/2014; and
- at the latest before the 01/28/2021.

***Date of Grant 06/24/2011***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BSA on the 12/23/2011;
- up to one fourth (1/4) of the BSA on the 12/23/2012;
- up to one fourth (1/4) of the BSA on the 12/23/2013;
- up to one fourth (1/4) of the BSA on the 12/23/2014; and
- at the latest before the 11/22/2021.

***Date of Grant 11/22/2011***

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 335 BSA on the 11/22/2012;
- up to 335 BSA on the 11/22/2013;
- up to 334 BSA on the 11/22/2014;

- up to 334 BSA on the 11/22/2015; and
- at the latest before the 11/22/2021.

***Details of BSA2010***

| Date of grant (Board of Directors) | 01/28/2011 | 01/28/2011 | 01/28/2011 | 01/28/2011 | 06/24/2011 | 06/24/2011 | 06/24/2011 | 06/24/2011 |
|---|---|---|---|---|---|---|---|---|
| Vesting period (years) | 0.9 | 1.9 | 2.9 | 3.9 | 0.5 | 1.5 | 2.5 | 3.5 |
| Plan expiration date | 01/27/2021 | 01/27/2021 | 01/27/2021 | 01/27/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 |
| Number of BSA2010 granted | 2,510 | 2,510 | 2,510 | 2,509 | 2,000 | 2,000 | 2,000 | 2,000 |
| Share entitlement per BSA2010(1) | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Exercise price | 77 | 77 | 77 | 77 | 77 | 77 | 77 | 77 |
| **Valuation method used** | **Black—Scholes** | | | | **Black—Scholes** | | | |
| Grant date share fair value | 77 | 77 | 77 | 77 | 77 | 77 | 77 | 77 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% | 40% | 40% | 40% |
| Average life of BSA2010 | 5.5 | 6.0 | 6.5 | 7.0 | 5.5 | 6.0 | 6.5 | 7.0 |
| Discount rate(2) | 2.70% | 2.82% | 2.82% | 3.04% | 2.55% | 2.68% | 2.68% | 2.87% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA | NA |
| Fair value per BSA2010 | 31.33 | 32.90 | 34.23 | 35.84 | 31.15 | 32.70 | 34.02 | 35.57 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BSA2010 warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BSA2010 plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSA2010.

| Date of grant (Board of Directors) | 11/22/2011 | 11/22/2011 | 11/22/2011 | 11/22/2011 |
|---|---|---|---|---|
| Vesting period (years) | 1.0 | 2.0 | 3.0 | 4.0 |
| Plan expiration date | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 |
| Number of BSA2010 granted | 335 | 335 | 334 | 334 |
| Share entitlement per BSA(1) | 15 | 15 | 15 | 15 |
| Exercise price | 77 | 77 | 77 | 77 |
| **Valuation method used** | | **Black—Scholes** | | |
| Grant date share fair value | 77 | 77 | 77 | 77 |
| Expected volatility | 40% | 40% | 40% | 40% |
| Average life of BSA | 5.5 | 6.0 | 6.5 | 7.0 |
| Discount rate(2) | 2.23% | 2.60% | 2.60% | 2.85% |
| Expected dividends | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA |
| Fair value per BSA | 30.70 | 32.58 | 33.89 | 35.54 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BSA2010 warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BSA2010 plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSA2010.

***Change in Number of BSA2010 Outstanding***

| | Year ended December 31, | | |
|---|---|---|---|
| **Number of BSA** | **2016** | **2017** | **2018** |
| Balance at beginning of period | 1,044 | 610 | 500 |
| Granted during the period | — | — | — |
| Forfeited during the period | — | — | — |
| Exercised during the period | 434 | 110 | — |
| Expired during the period | — | — | — |
| **Balance at end of period** | **610** | **500** | **500** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| Number of BSA2010 | Outstanding | Exercisable | Outstanding | Exercisable | Outstanding | Exercisable |
| BSA2010 with exercise price of €77 | 610 | 610 | 500 | 500 | 500 | 500 |
| **Total** | **610** | **610** | **500** | **500** | **500** | **500** |

**17.6 BSAX**

***Date of Grant 01/21/2009 and 06/25/2010***

The BSAX may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BSAX on the first anniversary of the date of grant;
- up to one fourth (1/4) of the BSAX on the second anniversary of the date of grant;
- up to one fourth (1/4) of the BSAX on the third anniversary of the date of grant;
- up to one fourth (1/4) of the BSAX on the fourth anniversary of the date of grant; and
- at the latest within ten (10) years from the date of grant.

By a decision by the Board of Directors meeting held on November 22, 2011, the BSAX warrants became exercisable beginning on the date of the first quotation of the shares of the Company on the Euronext regulated market in Paris.

***Details of BSAX***

| Date of grant (Board of Directors) | 01/21/2009 | 01/21/2009 | 01/21/2009 | 21/01/2009 | 06/25/2010 | 06/25/2010 | 06/25/2010 | 06/25/2010 |
|---|---|---|---|---|---|---|---|---|
| Vesting period (years) | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Plan expiration date | 01/20/2019 | 01/20/2019 | 01/20/2019 | 01/20/2019 | 06/24/2020 | 06/24/2020 | 06/24/2020 | 06/24/2020 |
| Number of BSAX granted | 77 | 77 | 77 | 75 | 457 | 457 | 456 | 455 |
| Share entitlement per BSAX(1) | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Exercise price | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 |
| **Valuation method used** | | | | **Black—Scholes** | | | | |
| Grant date share fair value | 70 | 70 | 70 | 70 | 70 | 70 | 70 | 70 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% | 40% | 40% | 40% |
| Average life of BSAX | 5.5 | 6.0 | 6.5 | 7.0 | 5.5 | 6.0 | 6.5 | 7.0 |
| Discount rate(2) | 2.71% | 2.98% | 2.98% | 3.11% | 2.04% | 2.23% | 2.23% | 2.50% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA | NA |
| Fair value per BSAX | 30.32 | 31.89 | 33.05 | 33.45 | 29.47 | 30.88 | 31.99 | 33.44 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BSAX warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BSAX plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BSAX.

***Change in Number of BSAX Outstanding***

| | Year ended December 31, | | |
|---|---|---|---|
| **Number of BSAX** | **2016** | **2017** | **2018** |
| Balance at beginning of period | 1,036 | 1,036 | — |
| Granted during the period | — | — | — |
| Forfeited during the period | — | — | — |
| Exercised during the period | — | 1,036 | — |
| Expired during the period | — | — | — |
| **Balance at end of period** | **1,036** | **—** | **—** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| **Number of BSAX** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** |
| BSAX with exercise price of €65 | 1,036 | 1,036 | — | — | — | — |
| **Total** | **1,036** | **1,036** | **—** | **—** | **—** | **—** |

**17.7 BCE2010**

***Date of Grant 06/24/2011***

The BCE may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BCE on the 12/23/2011;
- up to one fourth (1/4) of the BCE on the 12/23/2012;
- up to one fourth (1/4) of the BCE on the 12/23/2013;
- up to one fourth (1/4) of the BCE on the 12/23/2014; and
- at the latest within before the 11/22/2021.

***Date of Grant 11/22/2011***

The BSPCE may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BSPCE on the 11/22/2012;
- up to one fourth (1/4) of the BSPCE on the 11/22/2013;
- up to one fourth (1/4) of the BSPCE on the 11/22/2014;
- up to one fourth (1/4) of the BSPCE on the 11/22/2015; and
- at the latest within before the 11/22/2021.

***Details of BCE2010***

| **Date of grant (Board of Directors)** | **06/24/2011** | **06/24/2011** | **06/24/2011** | **06/24/2011** | **11/22/2011** | **11/22/2011** | **11/22/2011** | **11/22/2011** |
|---|---|---|---|---|---|---|---|---|
| Vesting period (years) | 0.5 | 1.5 | 2.5 | 3.5 | 1 | 2 | 3 | 4 |
| Plan expiration date | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 | 11/22/2021 |
| Number of BCE2010 granted | 6,000 | 6,000 | 6,000 | 6,000 | 2,510 | 2,510 | 2,510 | 2,509 |

| Date of grant (Board of Directors) | 06/24/2011 | 06/24/2011 | 06/24/2011 | 06/24/2011 | 11/22/2011 | 11/22/2011 | 11/22/2011 | 11/22/2011 |
|---|---|---|---|---|---|---|---|---|
| Share entitlement per BCE2010(1) | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Exercise price | 77 | 77 | 77 | 77 | 77 | 77 | 77 | 77 |
| **Valuation method used** | | | | **Black and Scholes** | | | | |
| Grant date share fair value | 77 | 77 | 77 | 77 | 77 | 77 | 77 | 77 |
| Expected volatility | 40% | 40% | 40% | 40% | 40% | 40% | 40% | 40% |
| Average life of BCE2010 | 5.5 | 6.0 | 6.5 | 7.0 | 5.4 | 5.9 | 6.4 | 6.9 |
| Discount rate(2) | 2.55% | 2.68% | 2.68% | 2.87% | 2.05% | 2.42% | 2.42% | 2.66% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA | NA |
| Fair value per BCE2010 | 31.16 | 32.71 | 34.03 | 35.58 | 30.42 | 32.29 | 33.58 | 35.2 |

(1) The number of shares takes into account an exercise parity adjusted by the division by 15 of the nominal value of the shares decided by the general meeting on December 9, 2011; each BCE2010 warrant now gives the right to subscribe to 15 new shares instead of 1 new share. For the same reason, the exercise price of each BCE2010 plan was adjusted as a result and is thus equal to 1/15th of the price initially determined by the general meeting that authorized each of the plans.

(2) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of BCE2010.

***Change in Number of BCE2010 Outstanding***

| Number of BCE2010 | Year ended December 31, 2016 | 2017 | 2018 |
|---|---|---|---|
| Balance at beginning of period | 15,974 | 12,339 | 11,005 |
| Granted during the period | — | — | — |
| Forfeited during the period | — | — | — |
| Exercised during the period | 3,635 | 1,334 | 3,839 |
| Expired during the period | — | — | — |
| **Balance at end of period** | **12,339** | **11,005** | **7,166** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| Number of BCE2010 | Outstanding | Exercisable | Outstanding | Exercisable | Outstanding | Exercisable |
| BCE2010 with exercise price of €77.00 | 12,339 | 12,339 | 11,005 | 11,005 | 7,166 | 7,166 |
| **Total** | **12,339** | **12,339** | **11,005** | **11,005** | **7,166** | **7,166** |

**17.8 OPTIONS**

***Grant of 09/18/2013***

The share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 518,000 SO (all the SO) on the fourth anniversary of the date of grant; and
- at the latest within ten (10) years from the date of grant.

***Grant of 06/03/2014***

The share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 75,000 SO (all the SO) on the 06/04/2016; and
- at the latest before the 06/03/2024.

***Grant of 06/23/2015***

The share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 30,000 SO on the 06/24/2016;
- up to 30,000 additional SO on the 06/24/2017;
- up to 30,000 additional SO on the 06/24/2018;
- up to 30,000 additional SO on the 06/24/2019;
- and at the latest before the 06/24/2025.

***Grant of 09/30/2015***

The 195,000 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% of the SO on the 09/30/2016;
- up to additional 25% of the SO on the 09/30/2017;
- up to additional 25% of the SO on the 09/30/2018;
- up to additional 25% of the SO on the 09/30/2019;
- and at the latest before the 09/30/2025.

***Grant of 12/15/2015***

The 75,000 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% of the SO on the 12/15/2016;
- up to additional 25% of the SO on the 12/15/2017;
- up to additional 25% of the SO on the 12/15/2018;
- up to additional 25% of the SO on the 12/15/2019;
- and at the latest before the 12/15/2025.

***Grant of 04/06/2016***

The 55,000 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 8,250 SO on the 04/021//2017;
- up to additional 8,250 SO on the 04/21//2018;
- up to additional 8,250 SO on the 04/21//2019;
- up to additional 8,250 SO on the 04/21//2020;
- up to 5,500 SO on the 05/02//2017;
- up to additional 5,500 SO on the 05/02//2018;
- up to additional 5,500 SO on the 05/02//2019;
- up to additional 5,500 SO on the 05/02//2020;
- and at the latest before 10 years of the date of the Grant.

***Grant of 06/21/2016***

The 154,100 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% of the SO as of one year after the Grant date;
- up to additional 12.5% of the SO as of 18 months after the Grant date;
- up to additional 12.5% of the SO as of 24 months after the Grant date;
- up to additional 12.5% of the SO as of 30 months after the Grant date;
- up to additional 12.5% of the SO as of 36 months after the Grant date;
- up to additional 12.5% of the SO as of 42 months after the Grant date;
- up to additional 12.5% of the SO as of 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

***Grant of 12/09/2016***

The 74,960 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 18,740 SO as of one year after the Grant date;
- up to additional 9,370 SO as of 18 months after the Grant date;
- up to additional 9,370 SO as of 24 months after the Grant date;
- up to additional 9,370 SO as of 30 months after the Grant date;
- up to additional 9,370 SO as of 36 months after the Grant date;
- up to additional 9,370 SO as of 42 months after the Grant date;
- up to additional 9,370 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

***Grant of 12/15/2016***

The 1,100 share options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% SO as of one year after the Grant date;
- up to additional 12.5% SO as of 18 months after the Grant date;
- up to additional 12.5 % SO as of 24 months after the Grant date;
- up to additional 12.5 % SO as of 30 months after the Grant date;
- up to additional 12.5 % SO as of 36 months after the Grant date;
- up to additional 12.5 % SO as of 42 months after the Grant date;
- up to additional 12.5 % 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

***Grant of 19,100 options as of 01/16/2017, 7,200 options as of 03/15/2017, 16,500 options as of 04/18/2017, 237,600 options as of 06/15/2017, 30,900 options as of 07/17/2017, 52,600 options as of 09/15/2017, 625,200 options as of 12/05/2017 and 8,300 options as of 12/15/2017.***

All the 2017 options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% SO as of one year after the Grant date;
- up to additional 12.5% SO as of 18 months after the Grant date;
- up to additional 12.5 % SO as of 24 months after the Grant date;
- up to additional 12.5 % SO as of 30 months after the Grant date;
- up to additional 12.5 % SO as of 36 months after the Grant date;
- up to additional 12.5 % SO as of 42 months after the Grant date;
- up to additional 12.5 % 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

***Grant of 15,500 options as of 01/15/2018, 16,500 options as of 04/16/2018, 16,500 options as of 05/15/2018, 23,600 options as of 06/15/2018.***

All these options may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 25% SO as of one year after the Grant date;
- up to additional 12.5% SO as of 18 months after the Grant date;
- up to additional 12.5 % SO as of 24 months after the Grant date;
- up to additional 12.5 % SO as of 30 months after the Grant date;
- up to additional 12.5 % SO as of 36 months after the Grant date;
- up to additional 12.5 % SO as of 42 months after the Grant date;
- up to additional 12.5 % 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

***Grant of 50,000 options as of 06/22/2018, 28,800 options as of 07/16/2018, 33,500 options as of 08/15/2018, 65,000 options as of 09/06/2018, 80,900 options as of 09/17/2018, 76,700 options as of 10/15/2018, 26,000 options as of 11/15/2018, 34,000 options as of 12/12/2018 and 7,200 options as of 12/17/2018.***

All the 2018 options From June 22, 2018 will be exercised by the beneficiary subject to the fulfillment of a presence condition and the following performance conditions : “ authorization to market Viaskin® Peanut by the US Food and Drug administration (FDA)” and on the basis of the following vesting schedule:

- up to 25% SO as of one year after the Grant date;

- up to additional 12.5% SO as of 18 months after the Grant date;
- up to additional 12.5 % SO as of 24 months after the Grant date;
- up to additional 12.5 % SO as of 30 months after the Grant date;
- up to additional 12.5 % SO as of 36 months after the Grant date;
- up to additional 12.5 % SO as of 42 months after the Grant date;
- up to additional 12.5 % 48 months after the Grant date;
- and at the latest before 10 years of the date of the Grant.

A turnover rate is applied per plan according to the characteristics and compositions of the plan.

***Details of SO***

| Date of grant (Board of Directors) | 09/18/2013 | 06/03/2014 | 06/23/2015 | 11/19/2015 | 01/04/2016 | 04/21/2016 | 05/02/2016 |
|---|---|---|---|---|---|---|---|
| Vesting period (years) | 4 | 2 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 09/18/2023 | 06/03/2024 | 06/23/2025 | 11/19/2025 | 01/04/2026 | 04/21/2026 | 05/02/2026 |
| Number of SO granted | 518,000 | 75,000 | 120,000 | 195,000 | 75,000 | 33,000 | 22,000 |
| Share entitlement per SO | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 7.57 | 19.01 | 48.9 | 66.06 | 65.68 | 62.82 | 59.04 |
| **Valuation method used** | | | | **Black—Scholes** | | | |
| Grant date share fair value | 7.9 | 19.01 | 48.9 | 66.06 | 65.68 | 62.82 | 58.62 |
| Expected volatility | 40% | 40% | 51% | 51% | 49.3%-49.8% | 49.4%-50.7% | 49.3%-50.6% |
| Average life of SO | 7 | 6 | 7 | 7 | 5-7 | 5-7 | 5-7 |
| Discount rate(1) | 1.72% | 0.89% | 0.89% | 0.81% | 0.39% | 0.04% | 0.10% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA |
| Fair value per SO | 3.57 | 7.46 | 25.28 | 34.05 | 29.5-32.6 | 28.3-30.9 | 26.4-28.8 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO.

| Date of grant | 06/21/2016 | 08/01/2016 | 09/15/2016 | 10/17/2016 | 11/15/2016 | 12/09/2016 | 12/15/2016 |
|---|---|---|---|---|---|---|---|
| Vesting period (years) | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 06/21/2026 | 08/01/2026 | 09/15/2016 | 10/17/2026 | 11/15/2026 | 12/09/2026 | 12/15/2026 |
| Number of SO granted | 110,000 | 10,000 | 9,300 | 16,500 | 8,300 | 74,960 | 1,100 |
| Share entitlement per SO | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 53.96 | 62.24 | 62.8 | 64.39 | 68.33 | 69.75 | 69.35 |
| **Valuation method used** | | | | **Black—Scholes** | | | |
| Grant date share fair value | 52.97 | 62.24 | 62.8 | 64.39 | 68.33 | 69.75 | 69.35 |
| Expected volatility | 49.1%-50.3% | 48.8%-49.8% | 48.6%-49.4% | 48.0%-48.9% | 47.8%-48.8% | 47.7%-48.5% | 40.44% |
| Average life of SO | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 |
| Discount rate(1) | -0.01% | -0.25% | -0.18% | -0.32%-0.15% | -0.11%+0.16% | -0.2%+0.18% | -0.18%+0.16% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA |
| Fair value per SO | 23.4-25.5 | 27.3-29.9 | 27.4-30.1 | 27.6-30.6 | 29.4-32.7 | 29.7-33.4 | 25.2-28.7 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO.

| Date of grant | 01/16/2017 | 03/15/2017 | 04/18/2017 | 06/15/2017 | 06/15/2017 | 07/17/2017 | 09/15/2017 |
|---|---|---|---|---|---|---|---|
| Vesting period (years) | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 01/16/2027 | 03/15/2027 | 04/18/2027 | 06/15/2027 | 06/15/2027 | 07/17/2027 | 09/15/2027 |
| Number of SO granted | 19,100 | 7,200 | 16,500 | 126,000 | 111.600 | 30,900 | 52,600 |
| Share entitlement per SO | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 66.11 | 66.25 | 60.77 | 59.05 | 60.54 | 71.61 | 74.22 |
| **Valuation method used** | | | | | | | |
| Grant date share fair value | 66.11 | 65.42 | 59.73 | 59.05 | 59.05 | 71.61 | 71.80 |
| Expected volatility | 40.21% | 39.82% | 39.63% | 39.23% | 39.23% | 38.84% | 38.57% |
| Average life of SO | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 |
| Discount rate(1) | -0.17%+0.19 % | +0.21%+0.61% | +0.02%+0.39% | -0.21%+0.07% | -0.21%+0.07% | +0.01%+0.34% | -0.14%+0.19% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA | NA |
| Fair value per SO | 23.9-27.2 | 23.6-27.1 | 21.2-24.2 | 20.8-23.6 | 20.4-23.22 | 25.3-28.2 | 24.3-27.8 |

| Date of grant | 12/05/2017 | 12/15/2017 | 01/15/2018 | 04/16/2018 | 05/15/2018 | 06/15/2018 |
|---|---|---|---|---|---|---|
| Vesting period (years) | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 12/05/2027 | 12/15/2027 | 01/15/2028 | 04/16/2028 | 05/15/2028 | 06/15/2028 |
| Number of SO granted | 625,200 | 8,300 | 15,500 | 16,500 | 16,500 | 23,600 |
| Share entitlement per SO | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 39.00 | 38.18 | 43.60 | 38.64 | 40.84 | 38.92 |
| **Valuation method used** | | | **Black—Scholes** | | | |
| Grant date share fair value | 35.73 | 36.43 | 43.60 | 38.64 | 40.84 | 35.48 |
| Expected volatility | 43.23% | 43.13% | 45.57% | 46.37% | 46.15% | 45.95% |
| Average life of SO | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 |
| Discount rate[(1)] | -0.23%+0.07% | -0.23%+0.07% | 0.32% | 0.35% | 0.41% | 0.23% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | NA | NA | NA | NA | NA | NA |
| Fair value per SO | 12.9-14.7 | 13.5-15.4 | 18.1-20.2 | 16.3-18.2 | 17.2-19.2 | 13.8-15.6 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO.

| Date of grant | 06/22/2018 | 07/16//2018 | 08/15/2018 | 09/17/2018 | 10/15/2018 | 11/15/2018 | 12/17/2018 |
|---|---|---|---|---|---|---|---|
| Vesting period (years) | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 06/22/2028 | 07/16/2028 | 15/08/2028 | 09/17/2028 | 10/15/2028 | 11/15/2028 | 12/17/2028 |
| Number of SO granted | 50,000 | 28,800 | 33,500 | 80,900 | 76,700 | 26,000 | 7,200 |
| Share entitlement per SO | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Exercise price | 37.22 | 33.81 | 32.90 | 40.94 | 37.28 | 32.57 | 26.76 |
| **Valuation method used** | | | | **Black and Scholes** | | | |
| Grant date share fair value | 34.32 | 32.16 | 32.90 | 40.94 | 31.74 | 28.66 | 26.76 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Expected volatility | 45.85% | 46.51% | 46.67% | 46.92% | 47.12% | 47.44% | 47.90% |
| Average life of SO | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 | 5-7 |
| Discount rate[1] | 0.19% | 0.14% | 0.17% | 0.27% | 0.37% | 0.29% | 0.26% |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | Yes[2] | Yes[2] | Yes[2] | Yes[2] | Yes[2] | Yes[2] | Yes[2] |
| Fair value per SO | 13.42-15.11 | 13.02-14.59 | 13.85-15.43 | 17.39-19.37 | 12.12-13.78 | 11.18-12.66 | 11.57-12.88 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO
(2) Performance conditions: Viaskin® Peanut's marketing authorization by the US Food and Drug Administration (U.S. FDA)

| **Date of grant** | **06/09/2018** | **11/29/2018** | **12/12/2018** |
|---|---|---|---|
| Vesting period (years) | 1-4 | 1-4 | 1-4 |
| Plan expiration date | 09/06/2028 | 11/29/2028 | 12/12/2028 |
| Number of SO granted | 65,000 | 350,000 | 34,000 |
| Share entitlement per SO | 1 | 1 | 1 |
| Exercise price | 36.96 | 30.02 | 27.96 |
| **Valuation method used** | | **Black and Scholes** | |
| Grant date share fair value | 36.96 | 27.44 | 27.96 |
| Expected volatility | 46.85% | 47.51% | 47.87% |
| Average life of SO | 5-7 | 5-7 | 5-7 |
| Discount rate[1] | 0.21% | 0.27% | 0.27% |
| Expected dividends | 0% | 0% | 0% |
| Performance conditions | Yes[2] | Yes[2] | Yes[2] |
| Fair value per SO | 15.65-17.43 | 11.08-12.47 | 12.09-13.46 |

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO
(2) Performance conditions: Viaskin® Peanut's marketing authorization by the US Food and Drug Administration (U.S. FDA)

***Change in Number of SO Outstanding***

| Number of SO | December 31, 2016 | 2017 | 2018 |
|---|---|---|---|
| Balance at beginning of period | 861,000 | 1,160,060 | 2,133,100 |
| Granted during the period | 359,060 | 998,500 | 824,200 |
| Forfeited during the period | 25,000 | 24,260 | 227,730 |
| Exercised during the period | 35,000 | 1,200 | 268,000 |
| Expired during the period | — | — | — |
| **Balance at end of period** | **1,160,060** | **2,133,100** | **2,461,570** |

***Breakdown of the Closing Balance***

| | Year ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2016 | | 2017 | | 2018 | |
| **Number of SO** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** | **Outstanding** | **Exercisable** |
| SO with exercise price of €7.57 | 471,000 | — | 471,000 | 471,000 | 203,000 | 203,000 |
| SO with exercise price of €19.01 | 40,000 | 40,000 | 40,000 | 40,000 | 40,000 | 40,000 |
| SO with exercise price of €48.90 | 120,000 | 45,000 | 120,000 | 75,000 | 120,000 | 90,000 |
| SO with exercise price of €66.06 | 170,000 | — | 170,000 | 85,000 | 170,000 | 127,500 |
| SO with exercise price of €65.68 | 75,000 | — | 75,000 | 18,750 | 75,000 | 37,500 |
| SO with exercise price of €62.82 | 33,000 | — | 33,000 | 8,250 | 22,000 | 11,000 |
| SO with exercise price of €59.04 | 22,000 | — | 22,000 | 5,500 | — | — |
| SO with exercise price of €53.96 | 110,000 | — | 101,300 | 24,425 | 87,500 | 54,687 |
| SO with exercise price of €62.24 | 10,000 | — | 10,000 | 2,500 | 10,000 | 5,000 |
| SO with exercise price of €62.80 | 9,300 | — | 9,300 | 2,325 | 9,300 | 4,650 |
| SO with exercise price of €64.39 | 16,500 | — | 9,300 | 2,325 | 9,300 | 4,650 |
| SO with exercise price of €68.33 | 8,300 | — | 8,300 | 2,075 | 8,300 | 4,150 |
| SO with exercise price of €69.75 | 74,960 | — | 72,900 | 18,225 | 51,995 | 25,997 |
| SO with exercise price of €66.35 | — | — | 1,100 | 275 | 1,100 | 550 |
| SO with exercise price of €66.11 | — | — | 19,100 | — | 19,100 | 7,162 |
| SO with exercise price of €66.25 | — | — | 7,200 | — | 7,200 | 2,700 |
| SO with exercise price of €60.77 | — | — | 16,500 | — | 7,200 | 2,700 |
| SO with exercise price of €59.05 | — | — | 118,500 | — | 91,000 | 34,125 |
| SO with exercise price of €60.54 | — | — | 111,600 | — | 111,600 | 41,850 |
| SO with exercise price of €71.61 | — | — | 30,900 | — | 7,200 | 1,800 |
| SO with exercise price of €74.22 | — | — | 52,600 | — | 45,400 | 11,350 |
| SO with exercise price of €39.00 | — | — | 625,200 | — | 540,075 | 135,018 |
| SO with exercise price of €38.18 | — | — | 8,300 | — | 8,300 | 2,075 |
| SO with exercise price of €43.60 | — | — | — | — | 8,300 | — |
| SO with exercise price of €38.64 | — | — | — | — | 16,500 | — |
| SO with exercise price of €40.84 | — | — | — | — | 16,500 | — |
| SO with exercise price of €38.92 | — | — | — | — | 23,600 | — |
| SO with exercise price of €37.22 | — | — | — | — | 50,000 | — |
| SO with exercise price of €33.81 | — | — | — | — | 28,800 | — |
| SO with exercise price of €32.90 | — | — | — | — | 33,500 | — |
| SO with exercise price of €36.96 | — | — | — | — | 65,000 | — |
| SO with exercise price of €40.94 | — | — | — | — | 80,900 | — |
| SO with exercise price of €37.28 | — | — | — | — | 76,700 | — |
| SO with exercise price of €32.57 | — | — | — | — | 26,000 | — |
| SO with exercise price of €30.02 | — | — | — | — | 350,000 | — |
| SO with exercise price of €27.96 | — | — | — | — | 34,000 | — |
| SO with exercise price of €37.24 | — | — | — | — | 7,200 | — |
| **Total** | **1,160,000** | **85,000** | **2,133,100** | **755,650** | **2,461,570** | **847,464** |

The exercise prices, anticipated lifetime, and fair value of the underlying shares based on the share price on the Euronext market on the grant date of the warrants were used for the valuation of each category of compensation in shares.

**17.9 FREE SHARES**

The 2012, 2013 and 2014 free shares are subject to a two-year vesting period.

***Details of Free Shares***

| Date of grant (Board of Directors) | 04/02/2012 | 07/25/2012 | 11/28/2012 | 07/25/2013&09/12/2013 | 06/03/2014 |
|---|---|---|---|---|---|
| Vesting period (years) | 2 | 2 | 2 | 2 | 2 |
| Number of free shares granted | 669,796 | 134,081 | 35,360 | 501,500 | 186,000 |
| Share entitlement per free share (1) | 1 | 1 | 1 | 1 | 1 |
| Grant date share fair value | 8.86 | 8.20 | 8.70 | 7.96 | 19.01 |
| Expected dividends | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | Yes(1) | Yes(1) | No | Yes(2) | Yes(3) |
| Expected turnover during the vesting period | 1% | 1% | 1% | 1% | 1% |

| Date of grant (Board of Directors) | 09/30/2015 | 12/15/2015 |
|---|---|---|
| Vesting period (years) | 2 | 2 |
| Number of free shares granted | 708,500 | 42,000 |
| Share entitlement per free share (1) | 1 | 1 |
| Grant date share fair value | 62.99 | 64.14 |
| Expected dividends | 0% | 0% |
| Performance conditions | Yes(4) | Yes(4) |
| Expected turnover during the vesting period | 0% | 0% |

(1) The acquisition of free shares is contingent for certain individuals (the "Key Managers"), including Dr. Benhamou, upon the achievement of the three performance criteria below:

- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) inclusion of the 100$^{th}$ patient in the VIPES phase II study.
- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) achievement of the principal evaluation criterion in the VIPES phase II study.
- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) inclusion of the first patient in the Viaskin® Milk phase II study.

(2) The acquisition of free shares is contingent for the Key Managers, including Dr. Benhamou, upon the achievement of the three performance criteria below:

- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) inclusion of the 100$^{th}$ patient in the Viaskin® Peanut phase III study a maximum of twelve (12) months after the inclusion of the first patient in the study.
- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) approval by the FDA of a protocol for the Phase III trial of Viaskin® Peanut.
- One-third of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) an increase of at least fifty (50) per cent for five (5) consecutive days of the Company's share price compared with the closing price of the Company's shares listed on Euronext Paris on the day of the adoption of the 2013 free share allocation plan, or July 25, 2013.

It is specified that in the event of a change of control of the Company (as defined in Article L. 233-3 of the Commercial Code), the performance criteria will be considered as definitively achieved.

(3) The acquisition of free shares is contingent for the Key Managers, including Dr. Benhamou, upon the achievement of the two performance criteria below:

- Half of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) inclusion of the 100th patient in the Viaskin® Peanut phase III study a maximum of twelve (12) months after the inclusion of the first patient in the study.
- Half of the shares allocated to Key Managers will only be acquired from the later of the two following dates (i) expiry of a period of two years from the date of allocation and (ii) approval by the FDA of a protocol for the Phase III trial of Viaskin® Peanut.

(4) The acquisition of free shares is contingent for all the employees, including Dr. Benhamou, upon the achievement of the three performance criteria below:

- One third of the shares will only be acquired from the later of the following two dates : (i) the end of the 2 year vesting period which runs from September 30, 2015 and (ii) achievement of the primary efficacy endpoint of the Phase III 'Pepites' trial for Viaskin® Peanut; the Board of Directors, during its meeting on February 15, 2018, decided that, following FDA's written responses to the clinical pre-BLA meeting package submitted by the Company, which reflected agreement on the content of the clinical module of the BLA for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age, the performance criteria was achieved.
- One third of the shares will only be acquired from the later of the following two dates : (i) the end of the 2 year vesting period which runs from September 30, 2015 and (ii) achievement of the primary efficacy endpoint of the Phase II 'Miles' trial for Viaskin® Milk.
- One third of the shares will only be acquired from until the later of the following two dates: (i) the end of the 2 year vesting period which runs from September 30, 2015 and (ii) the beginning of clinical testing of another product candidate from the Viaskin® platform.

| **Board of Directors**<br>**Grant date** | **04/06/2016** | **06/21/2016** | **08/16/2016** | **09/01/2016** | **10/27/2016** | **12/09/2016** |
|---|---|---|---|---|---|---|
| Vesting period (years) | 2 | 2 | 2 | 2 | 2 | 2 |
| Number of free shares granted | 63,750 | 193,000 | 10,000 | 5,000 | 15,000 | 23,600 |
| Share entitlement per free share | 1 | 1 | 1 | 1 | 1 | 1 |
| Grant date share fair value | 62.40 | 52.97 | 60.68 | 61.49 | 67.44 | 69.75 |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | yes(1) | yes(1) | yes(1) | yes(1) | yes(2) | yes(2) |
| Expected turnover during the vesting period | 0% | 0% | 0% | 0% | 0% | 0% |

(1) The acquisition of free shares is contingent for all the employees, including Dr. Benhamou, upon the achievement of the three performance criteria below:

- One third of the shares will only be acquired from the later of the following two dates: (i) the end of the 2 year vesting period which runs from Grant Date and (ii) achievement of the primary efficacy endpoint of the Phase III 'Pepites' trial for Viaskin® Peanut; the Board of Director, during its meeting on February 15, 2018, had decided that following the FDA's written responses to the clinical pre-BLA meeting package submitted by the Company, which reflected agreement on the content of the clinical module of the BLA for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age, the performance criteria was achieved.
- One third of the shares will only be acquired from the later of the following two dates: (i) the end of the 2 year vesting period which runs from Grant Date and (ii) achievement of the primary efficacy endpoint of the Phase II 'Miles' trial for Viaskin® Milk.
- One third of the shares will only be acquired from until the later of the following two dates: (i) the end of the 2 year vesting period which runs from Grant date and (ii) the beginning of clinical testing of another product candidate from the Viaskin® platform.

(2) The acquisition of free shares is contingent for key and new employees upon the achievement of the two performance criteria below:

- Half of the shares will only be acquired from the later of the following two dates: (i) the end of the 2 year vesting period which runs from Grant Date and (ii) achievement of the primary efficacy endpoint of the Phase III 'Pepites' trial for Viaskin® Peanut; the Board of Director, during its meeting on February 15, 2018, had decided that following the FDA's written responses to the clinical pre-BLA meeting package submitted by the Company, which reflected agreement on the content of the clinical module of the BLA for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age, the performance criteria was achieved.
- Half of the shares will only be acquired from the later of the following two dates: (i) the end of the 2 year vesting period which runs from Grant Date and (ii) achievement of the primary efficacy endpoint of the Phase II 'Miles' trial for Viaskin® Milk.

Performance conditions other than market conditions, which are taken into account by adjusting the number of equity instruments included in the measurement of the transaction amount, but are not taken into account when estimating the fair value of the shares.

| Board of Directors<br>Grant date | 03/14/2017 | 04/20/2017 | 06/22/2018 | 06/09/2018 | 01/11/2018 | 12/12/2018 | 17/12/2018<br>12/12/2018 |
|---|---|---|---|---|---|---|---|
| Vesting period (years) | 2 | 2 | 1 | 1 | 1 | 1 | 1 |
| Lockup period | 0 | 0 | 2 | 2 | 2 | 2 | 2 |
| Number of free shares granted | 22,500 | 24,000 | 486,153 | 450 | 57,000 | 16,250 | 3,000 |
| Share entitlement per free share | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Grant date share fair value | 68.07 | 61.20 | 34.32 | 36.96 | 33.33 | 27.96 | 26.76 |
| Expected dividends | 0% | 0% | 0% | 0% | 0% | 0% | 0% |
| Performance conditions | yes(1) | yes(1) | yes(2) | yes(2) | yes(2) | yes(2) | yes(2) |
| Expected turnover during the vesting period | 0% | 0% | 0% | 0% | 5% | 5% | 5% |

(1) The acquisition of free shares is contingent for key and new employees upon the achievement of the two performance criteria below:

- Half of the Shares allocated will not be acquired until the later of the following two dates: (i) the end of the two (2)-year acquisition period which runs from today and (ii) submission of the application for market authorization from the FDA for Viaskin® Peanut.
- Half of the Shares allocated will not be acquired until the later of the following two dates: (i) the end of the two (2)-year acquisition period which runs from today and (ii) the first date of sale of Viaskin® Peanut in the United States.

(2) The definitive allocation of the free shares will only occur at the later of the following two dates, subject to the presence requirement:

(i) expiry of the current acquisition period as from their initial allocation; and

(ii) approval of Viaskin® Peanut by the US Food and Drug Administration (U.S. FDA) (performance condition).

A turnover rate is applied for each instrument according to its respective characteristics and composition.

In December 2018, following the decision to voluntarily withdraw its application for BLA for Viaskin® Peanut for the treatment of peanut allergy in children 4 to 11 years of age, the expected dates of achievement of the performance conditions such as Viaskin® Peanut's marketing authorization by the FDA and the first date of sale of Viaskin® Peanut in the United States have been reviewed by the company. The spread of the IFRS 2 expense over the acquisition has been modified accordingly.

***Change in Number of Free Shares Outstanding***

| | Year ended December 31, | | |
|---|---|---|---|
| **Number of Free shares** | **2016** | **2017** | **2018** |
| Balance at beginning of period | 1,008,329 | 1,036,850 | 822,856 |
| Granted during the period | 310,350 | 46,500 | 562,853 |
| Forfeited during the period | 24,000 | 18,650 | 36,525 |
| Exercised during the period | 257,829 | 241,844 | 776,956 |
| Expired during the period | — | — | — |
| **Balance at end of period** | **1,036,850** | **822,856** | **572,228** |

**Note 18: Financial Revenue and Expenses**

The financial income and expenses are broken down as follows:

| | Year ended December 31, | | |
|---|---|---|---|
| | **2016** | **2017** | **2018** |
| | (Amounts in thousands of Euros) | | |
| Financial revenues | 1,646 | 616 | 493 |
| Financial expenses | (145) | (3,325) | (351) |
| **Total** | **1,500** | **(2,709)** | **141** |

The financial income mainly includes unrealized exchange effect of U.S.-dollar-denominated intercompany advances and capital gains on the disposals of investment securities. The foreign exchange losses and the expenses related to the accretion of the OSEO and BpiFrance advances are classified as financial expenses in the Consolidated Statements of (Loss).

**Note 19: Income Tax Expense**

As mentioned in Note 3.13—Accounting Principles—Other Income, the French Research Tax Credit is not included in the line item "Income taxes" but included in the line item "Other Income."

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

The following table shows the reconciliation between the effective and nominal tax expense at the nominal standard French rate of 33.33% as of December 31, 2016 and 2017 and 28.0% as of December 31, 2018 (excluding additional contributions):

| | Year ended December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| (Loss) before taxes | (114,531) | (147,692) | (166,061) |
| Theoretical group tax rate | 33,33% | 33,33% | 28,00% |
| Nominal tax expense | 38,173 | 49,226 | 46,497 |
| **Increase/decrease in tax expense arising from:** | | | |
| Permanent differences | — | — | — |
| Research tax credit | 2,409 | 3,110 | 3,089 |
| Share-based compensation | (11,451) | (10,260) | (7,253) |
| Non recognition of deferred tax assets related to tax losses and temporary differences | (29,195) | (41,453) | (54,205) |
| Other differences | 64 | 622 | 11,887 |
| Effective tax expenses | — | — | (15) |
| Effective tax rate | 0% | 0% | 0,01% |

**Deferred Tax Assets and Liabilities**

As mentioned in Note 3.15, the Company has not recognized deferred tax assets in the Consolidated Statements of Financial Position. The amount of the losses carried forward at the end of December 2018 is €531 million including €527 million for DBV Technologies S.A.

**Note 20: Commitments**

***Obligations Under the Terms of the Ordinary Rental Agreements***

The principal offices of the Company occupy a 4,770 square meter facility consisting of office and laboratory space, pursuant to a lease agreement dated March 3, 2015, which expires on March 8, 2024. The Company also has a second facility in Bagneux, France, which was its former corporate headquarters. This facility consists of 1,479 square meters of office and laboratory space and is used primarily by the Company's industrial and production teams. This lease expires on May 31, 2020. A new addendum for the period 2020 to 2029 was signed on April 13, 2018. An additional lease for offices in Montrouge (France) was signed on June 4, 2018.

The Company has an office in North America to support the U.S. subsidiary as well as future commercialization needs. The Company subleased 3,913 square feet of office space in New York, New York. This sublease expired on June 30, 2017. The Company entered into a similar lease agreement on November 2017. The Company subleases 3,780 square feet of office space in New York, New York. The sublease was signed for an initial period of 5 years.

The Company also leases a commercial facility of 8,919 square feet in Summit, New Jersey, which is intended to support the manufacturing needs through the launch and commercialization of Viaskin® Peanut in North America, if the appropriate regulatory approvals are received. This lease commenced on September 19, 2016 for a period of eight years and four months. This lease includes extension options of two to five-year periods. An additional lease for the US subsidiary's office space in Summit, New Jersey was signed on July 11, 2018.

The amount of future rents and charges in that capacity breaks down as follows at December 31, 2018:

| | 12/31/2018 |
|---|---|
| 2019 | 3,965 |
| 2020 | 4,047 |
| 2021 | 4,064 |
| 2022 | 4,058 |
| 2023 | 3,785 |
| 2024 | 3,211 |
| 2025 | 1,998 |
| 2026 | 2,014 |
| 2027 | 1,700 |
| 2028 | 1,031 |
| 2029 | 393 |
| **Total** | **30,267** |

The Company has signed various ordinary rental agreements for office equipment and vehicles. The future rental payments as at December 31, 2018 are as follows:

- 2019: €77 thousands;
- 2020: €70 thousands;
- 2021: €16 thousands.

***Obligations Under the Terms of Other Agreements***

The Company signed with its bank CIC an acquisition contract of monetary market fund "SICAV CM-CIC" pledged as a guarantee for the ordinary rental agreements of the premises of Bagneux for an amount of €0.4 million.

The Company also signed a letter of credit to ensure the sub-lease of its premises of its New York subsidiary company for $164 thousand due on March 17, 2015. This credit note has not been extended for an additional year in 2016.

A letter of credit has also been signed by the Company in April 2016 for $143 thousand to ensure the lease of its premises of its Summit (NJ) subsidiary. This credit note has been extended for an additional year.

A letter of credit has also been signed by the Company in May 2017 for $300 thousands to ensure the lease of its premises of its New York subsidiary.

The Company took in 2015 a term deposit for a sum of €227 thousand over 3 years.

In addition, the Company has subscribed a €3,500 thousand term deposit with the CIC banking institution as collateral for a foreign exchange pledged security up to €50 million.

As it has sub-contracted several important functions, the Company has been required to conclude, within the framework of its current operations, sub-contracting contracts or short- or medium-term delegation contracts with various third parties, in France and abroad, which include various obligations that are usual in these circumstances.

Within the context of launching its clinical studies for Viaskin® Peanuts and Viaskin® Milk products, the Company signed agreements with several contract research organizations (CRO).

The ongoing studies amount globally to €101.3 million. As of December 31, 2018, the amount remaining to pay as part of these contracts until year ended 2021 is €34.9 million.

On January 7, 2009, the Company entered into an assignment, development and co-ownership agreement with Public Welfare-Hospitals of Paris (L'Assistance Publique—Hopitaux de Paris), or AP-HP, and Université Paris-Descartes, or UPD, by which the Company agreed to terms of co-ownership with AP-HP and UPD of certain U.S. and foreign patents and patent applications, referred to herein as the shared patents. The Company, and any licensees or sublicensees the Company designates, have the exclusive right to commercial uses of the shared patents. AP-HP and UPD agreed to use the shared patents only for internal research purposes and not to license the shared patents to any third party. Upon commercialization of any product covered by the shared patents, which the

Company expects would include its Viaskin® product candidates, the Company will be obligated to pay AP-HP and UPD a percentage of net sales as a royalty. This royalty varies depending on the particular patent used in the product and is in the low single digits. Additionally, if the Company licenses any of the shared patents to a third party and a licensee commercializes products covered by such shared patents, the Company will be obligated to pay AP-HP and UPD a percentage in the low single digits of the money it receives from its licensee. If the Company does not sell any of its product candidates covered by the shared patents within 30 months from the date it first markets such product candidates, AP-HP may, upon six months' notice and subject to certain exceptions, convert its exclusive right to the commercial use of the shared patents to a non-exclusive right. Any party may terminate the license in the event of another party's substantial breach which remains uncured after six months of receiving written notice of such breach. The agreement will also terminate in the event the Company ceases operations or is subject to a dissolution or bankruptcy proceedings. Absent early termination, the agreement will automatically terminate upon the expiration of the last shared patent. In the event the agreement is terminated, the Company would no longer have the exclusive right to commercial use of the shared patents, though it would retain its shared ownership rights. In addition, its ownership stake in certain jointly made improvements covered by the shared patents would survive termination of the agreement. The longest lived patent rights licensed to the Company under the agreement are currently expected to expire in 2028. To date, this agreement has not had an impact on the Company's financial statements.

**Note 21: Relationships with Related Parties**

The compensation amounts for 2018 presented below, which were awarded to the Corporate Officers and the members of the Executive Committee of the Company totals 17.4 million euros.

Following the reorganization of the Company at the beginning of 2015, the Company henceforth considered the members of the Executive Committee to be related parties.

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Corporate officers | 714 | 745 | 1,496 |
| Executive committee | 2,268 | 2,184 | 3,325 |
| Directors' fees | 195 | 407 | 469 |
| Share-based payments to members of the Board of Directors | 13,714 | 12,018 | 12,189 |
| **Total** | **16,891** | **15,353** | **17,478** |

In accordance with the decisions of the Board of Directors of September 25, 2012 and April 6, 2016, following the termination of the Chief Executive Officer, Mr. Pierre-Henri Benhamou, and after having noted that the payment conditions were fulfilled, the Board of Directors during its meeting held on November 28, 2018 decided the payment of the severance amounting a total of 876 thousand euros.

The methods for the valuation of the benefit related to share-based payments are presented in Note 17.

The company has entered into agreements with some of its directors, particularly in the context of its commercial deployment in the United States. The expense recognized for these contracts amounted to 49 thousand euros at December 31, 2018 compared to 45 thousand euros at December 31, 2017.

As part of its commercial rollout in the United States, the Company entered into an agreement in December 2016 with one of its Directors for Commercial strategy consulting works. The expenses recorded in 2018 and in 2017 as part of this agreement amounts respectively €45 thousands.

A schedule of amounts payable to related parties:

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Compensation | 767 | 689 | 66 |
| Directors' fees | 195 | 432 | 469 |
| Pension obligations | 342 | 402 | 419 |
| **Total** | **1,304** | **1,523** | **954** |

**Note 22: Earnings Per Share**

Taking into account the division of the nominal value of shares of the Company by 15, which was decided by the annual general meeting on December 9, 2011 the amount of shares is adjusted, and multiplying it by 15, for all the outstanding shares presented. The basic earnings per share is calculated by dividing the net income going to the shareholders of the Company by the weighted average number of common shares outstanding during the course of the fiscal year. The weighted average number of shares was 24,454,850 in 2016. The weighted average number of shares was 24,757,176 in 2017. The weighted average number of shares was 28,924,976 in 2018.

The instruments that entitle their holders to a portion of the share capital on a deferred basis (BSAs, BSPCEs) are considered to be anti-dilutive (2,360,945 instruments in 2016, 3,309,539 instruments in 2017 and 3,366,296 instruments in 2018). These instruments are presented in detail in Note 17. Therefore, the diluted earnings per share are identical to the basic earnings per share.

| | December 31, | | |
|---|---|---|---|
| | 2016 | 2017 | 2018 |
| | (Amounts in thousands of Euros) | | |
| Net income of the reporting period | (114,531) | (147,693) | (166,076) |
| Adjusted weighted average number of outstanding shares | 24,454,850 | 24,757,176 | 28,924,976 |
| **Basic / Diluted earnings per share (€/share)** | **(4.68)** | **(5.97)** | **(5.74)** |

**Note 23: Management of Financial Risks**

The principal financial instruments of the Company are comprised of financial assets, cash, and investment securities. The purpose of managing these instruments is to allow the business activities of the Company to be financed. It is not the Company's policy to subscribe to financial instruments for speculative purposes. The Company does not utilize derivatives.

The principal risks to which the Company is exposed are liquidity risk, interest rate risk and credit risk.

***Liquidity Risk***

As of December 31, 2018, the Company had €122.8 million in cash and cash equivalents compared to €137.9 million of cash and cash equivalents as of December 31, 2017. The Company has incurred operating losses and negative cash flows from operations since inception, incurred a net loss of €166.1 million during the year ended December 31, 2018, and has an accumulated deficit and reserves of €254.9 million as of December 31, 2018. Net cash used in operating activities was €136.6 million for the year ended December 31, 2018 and €114.3 million for the year ended December 31, 2017.

The Company has primarily funded these losses through equity financings, and by obtaining public assistance in support of innovation and reimbursements of research tax credit. To date, the Company has not generated any product revenue and the Company continues to prepare for the potential launch of its Viaskin® Peanut product candidate in North America planned in 2020 for which its BLA submission to the US FDA is expected in the third quarter of 2019. The Company expects operating losses to continue for the foreseeable future. Current cash-on-hand and cash equivalents are not projected to be sufficient to support the operating plan for the next 12 months despite additional funds raised in March 2018. The Company expects to be short in cash during the fourth quarter of 2019. As such, there is substantial doubt regarding Company's ability to continue as a going concern.

The Company expects to seek additional funds, most likely from equity and/or debt financings. However, no assurance can be given at this time as to whether the Company will be able to achieve these financing objectives.

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

***Interest Rate Risk***

The Company's exposure to interest-rate risk primarily involves investment securities. These are composed of money market funds and time deposit accounts. Changes in interest rates have a direct impact on the rate of return on these investments and the cash flows generated.

The Company has no variable rate debt. The repayment flows of its debts are not subject to interest rate risk.

The repayment of the conditional advances may vary depending on whether or not objectives are attained. The change in the flows of the anticipated repayments is treated in the income statement (Note 3.10).

As of this date, the Company has not contracted borrowings from credit institutions and, therefore, has only very low exposure to interest rate risk.

***Credit Risk***

The credit risk related to the cash, the cash equivalents, and the current financial instruments is not significant in light of the quality of the co-contracting financial institutions.

***Fair Value***

The fair value of financial instruments traded on an active market, such as the securities available for sale, is based on the market rate as of the closing date. The market prices used for the financial assets owned by the Company are the bid prices in effect on the market as of the valuation date.

The nominal value, less the provisions for depreciation, of the accounts receivable and current debts, is presumed to approximate the fair value of those items.

***Foreign Exchange Risk***

The Company is exposed to a very insignificant foreign exchange risk inherent in some of its supplies obtained in the United States, which have been invoiced in US dollars. As of this date, the company does not make sales revenue in dollars or in any other currency other than the euro; the Company does not receive any full or partial mechanical endorsement. The exposure to currencies other than the U.S. dollar is negligible.

For 2018, approximately 34% of our purchases and other external expenses have been made in U.S. dollars compared with less than 12% in 2017 and 2016. Exchange rate effects have a non-significant impact on the Group's consolidated net position. At this stage, the company has not put in place any hedging instruments.

In light of these insignificant amounts, the Company has not adopted, at this stage, a hedging mechanism in order to protect its business activity against fluctuations in exchange rates. The Company cannot rule out the possibility that a significant increase in its business, particularly in the United States, may result in greater exposure to exchange rate risk and should thus consider adopting an appropriate policy for hedging against these risks.

**Note 24: Events After the Close of the Fiscal Year**

On January 3, 2019, the Company announced the following changes to its leadership team as the Company strengthens its organizational competencies in the development of the Viaskin® platform:

- DBV's Chief Scientific Officer (CSO), Dr. Hugh Sampson, assumed the role of interim Chief Medical Officer (CMO) effective on January 3, 2019. Dr. Sampson succeeded Dr. Lucia Septien-Velez, who decided to leave the Company to pursue other opportunities. As CSO and interim CMO, Dr. Sampson leads both the scientific and medical teams at the Company and reports to Daniel Tassé, Chief Executive Officer of DBV Technologies.
- Following recent interactions with the U.S. Food and Drug Administration (FDA), Julie O'Neill, a member of DBV's Board of Directors, was engaged to direct all product development, manufacturing, supply chain, quality assurance, and end-to-end process optimization at the Company. She directly advises Daniel Tassé. Julie, who was appointed to DBV's Board of Directors in 2017, continues to serve as a director, while overseeing the anticipated submission of the Viaskin® Peanut BLA in children 4 to 11 years of age. Most recently, Julie was Executive Vice President, Global Operations for Alexion Pharmaceuticals Inc.

A class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint alleges that the Company and its former Chief Executive Officer, its current Chief Executive Officer and its Deputy Chief Executive Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The plaintiff seeks unspecified damages on behalf of a purported class of purchasers of our securities between February 14, 2018 and December 19, 2018. The Company believes that the allegations contained in the complaint are without merit and intend to defend the case vigorously. However, whether or not the plaintiff's claims are successful, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of the Company's business. If the Company is ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect its operations.

The Company may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert management's attention and resources, which could cause serious harm to the Company's business, operating results and financial condition. The company maintains liability insurance; however, if any costs or expenses associated with this or any other litigation exceed its insurance coverage, the Company may be forced to bear some or all of these costs and expenses directly, which could be substantial.

On February 13, 2019, the Company announced that expects to resubmit its BLA for Viaskin® Peanut for the treatment of peanut allergic children 4 to 11 years of age in the third quarter of 2019.

On March 4, 2019, the board of directors appointed existing board member, Michel de Rosen, as Non-Executive Chairman of the board. Mr. de Rosen succeeds the Company's co-founder, Dr. Benhamou, who retired from his position as DBV's Non-Executive Chairman and board member. Dr. Benhamou joined the Company's Scientific Advisory Board on March 4, 2019. Additionally, Mr. Tassé was appointed to the board of directors, replacing Dr. Benhamou. With these changes, DBV's board of directors currently consists of eight directors.

On March 5, 2019, the Company also provided an update on leadership and operational changes:

- Charles Ruban, former Chief Operating Officer, who oversaw regulatory, product development and commercial operations, resigned from the Company to pursue new opportunities, effective March 15, 2019.
- Laurent Martin, former Chief Development Officer, resigned from his regulatory and product development role, effective March 15, 2019. Mr. Martin continues to serve as DBV's Pharmacien Responsable (Responsible Pharmacist) in accordance with applicable regulations in France while a search for a replacement is planned.
- Kevin Trapp, Chief Commercial Officer, currently reports to Mr. Tassé. In addition, Mr. Martin's primary responsibilities were assumed by Julie O'Neill, DBV's manufacturing and operations leader, who oversees product development, manufacturing, supply chain, quality assurance, and end-to-end process optimization at the Company. As announced in January 2019, Ms. O'Neill reports to Mr. Tassé.

The company believes these changes in leadership will flatten the organizational structure to support its evolution from a late-stage research and development company into a potentially commercial-stage company.

The Company may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert management's attention and resources, which could cause serious harm to the Company's business, operating results and financial condition. The company maintains liability insurance; however, if any costs or expenses associated with this or any other litigation exceed its insurance coverage, the Company may be forced to bear some or all of these costs and expenses directly, which could be substantial.

The Company evaluated all other subsequent events that occurred after December 31, 2018 through the date of issuance of the consolidated financial statements and determined there are no other significant events that require adjustments or disclosure.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

**DBV Technologies S.A.**

/s/ Daniel Tassé
Name: Daniel Tassé
Title: Chief Executive Officer
*(Principal Executive Officer)*

Date: April 1, 2019

**Exhibit 4.5**

**[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

CONFIDENTIAL Execution Copy

# AMENDMENT TO THE DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT

This AMENDMENT (the "Amendment") entered into on 12 July 2018 (the "Effective Date") is an amendment to the DEVELOPMENT COLLABORATION AND LICENSE AGREEMENT dated 27th day of May, 2016, by and between NESTEC S.A., with a place of business at Avenue Nestlé 55, 1800 Vevey, Switzerland ("NESTEC") and DBV TECHNOLOGIES, S.A., with a place of business at 177-181 avenue Pierre Brossolette 92120 Montrouge France ("DBV") (the "Agreement"). NESTEC and DBV may each be referred to herein individually as a "Party" and collectively as the "Parties."

Capitalized terms that are used bur not defined in this Amendment shall have the meaning ascribed to this term in the Agreement.

## RECITALS

**WHEREAS**, the collaboration between DBV and NESTEC has progressed and the Parties have agreed to adjustments, as follows based on the revised Work Plan agreed between the Parties.

## AGREEMENT

### 1. Changes to Clause 8.2.1.

The Parties agree that section 8.2.1. shall hereby be replaced in its entirety by the following provisions:

Development Milestones. NESTEC shall pay to DBV the following non-creditable, non-refundable payment for the first achievement of the following milestone events for the Licensed Product (each, a "Development Milestone"):

| Development Milestone Event / Target Date | Payment |
|---|---|
| 1. [***] | €[***] |
| 2. [***] | €[***] |
| 3. [***] | €[***] |
| 4. [***] | €[***] |
| 5. [***] | €[***] |
| 6. [***] | €[***] |

| Development Milestone Event / Target Date | Payment |
|---|---|
| 7. [***] | €[***] |
| 8. [***] | €[***] |
| 9. [***] | €[***] |
| 10. [***] | €[***] |
| **TOTAL Amount of Development Milestones Payments:** | **€[***]** |

The Parties acknowledge that the milestones set forth in (1) and (2) have been achieved as of the Effective Date and that the corresponding amounts have been duly paid by NESTEC to DBV as of the Effective Date.

Further to the milestones set forth in (1) to (10) above, NESTEC agrees to pay further development milestones of up to €[***].

If any of the milestones set forth in (6), (7) or (8) is achieved whereas any of the milestones set forth in (3) to (6) has not been achieved, then the applicable milestones set forth in (3), (4) (5) and (6) shall become payable upon achievement of the milestone set forth in (6), ( 7) or (8). If the milestone set forth in (5) is achieved whereas any of the milestones set forth in (3) or (4) has not been achieved, then the applicable milestones set forth in (3) and (4) shall become payable upon achievement of the milestone set forth in (5).

Each milestone payment set forth in this Section 8.2.1 shall be payable by NESTEC within [***] after the first achievement of the applicable Development Milestone for the Licensed Product. If requested by NESTEC, DBV will provide NESTEC with a corresponding invoice for each Development Milestone payment due.

[***].

## 2. Miscellaneous

2.1 Entire Agreement. This Amendment amends and supersedes any conflicting provisions of the Agreement, and forms an entire part of the Agreement. Together with the Agreement, it constitutes the entire agreement between the Parties and shall cancel and supersede any and all prior and contemporaneous negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof.

2.2 Counterparts. This Amendment may be executed in more than one counterpart (including by electronic transmission), each of which shall be deemed an original, but all of such counterparts taken together shall constitute one and the same agreement.

2.3 Governing Law. Any dispute, claim or controversy arising under or related to this Amendment, including the construction, validity and performance of this Agreement, shall be governed in all respects by the substantive laws of France.

*[Signature page follows.]*

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

For DBV TECHNOLOGIES

/s/ Pierre-Henri Benhamou

**By: Dr Pierre-Henri BENHAMOU**
Chairman and CEO

For NESTEC S.A.

/s/ Claudio Kuoni

**By: Claudio Kuoni**
General Counsel Nestlé Health Science

**Exhibit 4.17**

**DBV TECHNOLOGIES S.A.**
**NONQUALIFIED STOCK OPTION GRANT NOTICE**
**(2018 OPTIONS)**

The Combined Annual General Meeting of Shareholders of DBV Technologies (the *"**Company**")* of June 22, 2018 (the "***Annual General Meeting***") authorized the Company's Board of Directors (the ***"Board"***) to grant options giving entitlement to shares of the Company to the persons that it may name from among the members of staff and officers of the Company and of companies associated with it subject to the terms of Article L.225-180 of the French Commercial Code.

Pursuant to (i) this authorization, the Board decided at its meeting of June 22, 2018, the policy for allocation of Stock options to employees and Corporate Officers of the subsidiaries outside France according to their grade and the main characteristics of an options plan conferring the entitlement to subscribe to shares of the Company, known as "*DBV Technologies S.A. Stock Option Agreement*". The Board delegated all power to the Chairman & CEO and to the Deputy CEO for the purpose of implementing this policy including the certification of the allocation decision upon the 15th of the month following the effective date of employment or an employment contract, the purchase price for options and the numbers of shares allocated to each Optionee.

Pursuant to **(i)** this delegation, the CEO hereby grants to the Optionee named below an option (the "***Stock Option***") to purchase/subscribe on or prior to the Expiration Date specified below all or part of the number of shares of the Company's Ordinary Shares, €0.10 nominal value per share (each, a "***Share***"), specified below at the Option Exercise Price per Share specified below subject to the terms and conditions set forth herein, in the attached Stock Option Agreement and Plan (the "***Agreement and Plan***"), all of which are incorporated herein in their entirety. This Stock Option is not intended to be an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended, with respect to Optionees who are US tax residents.

| | | |
|---|---|---|
| Name of Optionee: | _____ | (the "***Optionee***") |
| No. of Options: | _____ | |
| No. of Shares: | _____ | |
| Grant Date: | _____ | [1] |
| Expiration Date: | _____ | (the "***Expiration Date***")[2] |
| Option Exercise Price/Share: | €_____ | (the "***Option Exercise Price***")[3] |

[1] Grant Date will generally be the 15th day of the month following the employee's hire date (*i.e.* if effective date before the 15th, it will be the 15th of the current month; if the effective date after the 15th, it will be the 15th of the following month). if the 15th is not a business day, the Grant date will be the first following business day.

[2] Insert date that is 10 years from Grant Date.

[3] Shall equal the closing price of the share on the Euronext Paris on the day that the Grant is recorded, but will not be less than the average of the share prices quoted over the 20 trading days preceding the date of said grant.

Vesting Schedule: 25 percent of the Shares subject to this Stock Option shall vest on the first anniversary of the Grant Date, subject to the Optionee's Continuous Service through such date. Thereafter, the remaining 75 percent of the Shares shall vest in six substantially equal bi-annual installments following the first anniversary of the Grant Date, subject to the Optionee's Continuous Service through each such date, as set forth in the Agreement and Plan.

Exercise conditions: the exercise of this Stock Option is subject to (i) the existence of Continuous Service at the date of exercise of the said Stock Option in accordance with this Agreement and Plan (and subject to any exception set forth in the Plan) and (ii) the Company having obtained the marketing approval from US Food and Drug Administration (U.S. FDA) of Viaskin Peanut.

**Additional Terms/Acknowledgements:** Optionee acknowledges receipt of, and understands and agrees to, this Grant Notice (as defined in this Agreement and Plan), this Agreement and Plan. Optionee acknowledges and agrees that this Grant Notice and this Agreement and Plan may not be modified, amended or revised except as provided herein. Optionee further acknowledges that as of the Date of Grant, this Grant Notice and this Agreement and Plan set forth the entire understanding between Optionee and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionee or (ii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

This Grant Notice is not to be interpreted as a guarantee or contract of Continuous Service (as defined in this Agreement and Plan).

By accepting this option, Optionee consents to receive such documents by electronic delivery and to participate in this Agreement and Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

**DBV TECHNOLOGIES, S.A.**

By: _____
Signature
Title: _____
Date: _____

**OPTIONEE:**

_____
Signature
Date: _____

**DBV TECHNOLOGIES S.A.**
**STOCK OPTION AGREEMENT AND PLAN**

Pursuant to the Stock Option grant notice (the "***Grant Notice***") and this Stock Option agreement (this "***Agreement and Plan***"), DBV Technologies (the "***Company***") has granted Optionee an option (the "***Stock Option***") under this Agreement and Plan referenced in the Grant Notice to purchase/subscribe the number of shares of the Company's Ordinary Shares, €0.10 nominal value per share (each, a "***Share***") indicated in the Grant Notice at the exercise price indicated in the Grant Notice. The Stock Option is granted to the Optionee effective as of the date of grant set forth in the Grant Notice (the "***Grant Date***"). Capitalized terms in this Agreement shall have the meaning specified in the Grant Notice unless a different meaning is specified herein.

The details of the Stock Option and this Agreement and Plan generally, in addition to those set forth in the Grant Notice, are as follows:

1. Legal Framework.

(a) The Combined Annual General Meeting of Shareholders of the Company of June 22, 2018 (the "***Annual General Meeting***") authorized the Board to grant options to purchase and/or subscribe Shares to the persons that it may name from time-to-time among the members of staff and officers of the Company and of companies associated with it subject to the terms of Article L.225-180 of the French Commercial Code (the "***French Code***"). This authorization was given for a period of 18 months from the Annual General Meeting, under the provisions of Articles L.225-177 *et seq.* of the French Code.

(b) This Agreement and Plan and this Stock Option shall be administered by the Board. The Board may change the details of this Agreement and Plan and this Stock Option (including the Grant Notice) (i) if it considers that the change is appropriate and has no significant negative impact on the interests of the Optionees or (ii) with the agreement of the Optionees concerned. More generally, in case of a change in the legislation, regulations or accounting standards, or a change in the interpretation of such provision, particularly relating to the tax or social security arrangements for the allocation or exercise of options, the terms and conditions for the options under this Agreement and Plan, including this Stock Option, may be amended by the Board at its discretion, to respond to this change as it sees fit. By way of example, the Board might decide to shorten or extend the exercise period, or to introduce a mandatory retention period.

(c) The Board will have the power, subject to, and within the limitations of, the express provisions of this Agreement and Plan: (i) to construe and interpret this Agreement and Plan and this Stock Option (including the Grant Notice) and (ii) to settle all controversies regarding this Agreement and Plan and awards granted under it, including this Stock Option.

(d) The Board may delegate some or all of the administration of this Agreement and Plan to the Company's Chief Executive Officer, provided such delegation complies with French law. The Board may retain the authority to concurrently administer this Agreement and Plan with the Chief Executive Officer and may, at any time, revest in the Board some or all of the powers previously delegated.

(e) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

2. Vesting. Subject to the provisions contained herein, the Stock Option will vest as provided in the Grant Notice and as set forth below during a planned vesting period of four (4) years:

- 0% of the total number of Stock Options granted to the Optionee shall vest between the Grant Date and the first anniversary date of the Grant Date (excluded);
- 25% of the total number of Stock Options granted to the Optionee shall vest as from the first anniversary date of the Grant Date (included);
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after eighteen (18) months as from the Grant Date;
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after twenty-four (24) months as from the Grant Date;
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after thirty (30) months as from the Grant Date;
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after thirty-six (36) months as from the Grant Date;
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after forty-two (42) months as from the Grant Date; and
- an additional 12.5 % of the total number of Stock Options granted to the Optionee shall vest after forty-eight (48) months as from the Grant Date.

Vesting will cease upon the termination of Optionee's Continuous Service, unless otherwise provided below. Upon a Takeover, the Stock Options will be deemed 100% vested and exercisable.

The Stock Options are exercisable within a ten (10) year period as from the Grant Date and in accordance with the provisions of this Agreement and Plan.

3. Number of Shares and Exercise Price. The number of Shares subject to this Stock Option and the Option Exercise Price are set forth in the Grant Notice. As provided for in the Grant Notice, each Stock Option shall give entitlement to acquire/subscribe to one (1) Share, subject to adjustments provided for in Section 10 below.

For the avoidance of doubt, it is specified that the Option Exercise Price shall correspond to the price of the Shares on Euronext Paris on the Grant Date, but will not be less than the average of the share prices quoted over the twenty (20) trading days preceding the Grant Date.

4. Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option and in accordance with the terms of this Stock Options, the Optionee may give written notice to the Company of his or her election to purchase/subscribe some or all of the Shares subject to this Stock Option purchasable/being available to subscription at the time of such notice. This notice shall specify the number of Shares to be purchased/subscribed.

(b) Payment of the purchase price for the Shares may be made in cash, by certified or bank check or other instrument acceptable to the Board or, if allowable under applicable law, by way of offsetting receivables held by the Optionee against the Company.

(c) Payment instruments will be received subject to collection. The transfer to the Optionee on the records of the Company or of the transfer agent of the Shares will be contingent upon (i) the Company's receipt from the Optionee of the full purchase/subscription price for the Shares, as set forth above, (ii) the fulfillment of any other requirements contained herein or in this Agreement and Plan or in any other agreement or provision of laws, and (iii) the receipt by the Company of any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Shares to be purchased/subscribed pursuant to the exercise of Stock Options under this Agreement and Plan and any subsequent resale of the Shares will be in compliance with applicable laws and regulations.

(d) The Shares purchased/subscribed upon exercise of this Stock Option shall be transferred to the Optionee on the records of the Company or of the transfer agent upon compliance to the satisfaction of the Board with all requirements under this Agreement and Plan, applicable laws or regulations in connection with such transfer and with the requirements hereof. The determination of the Board as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any Shares subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company shall have transferred the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such Shares. Such Shares shall be freely transferable once the Stock Option has been exercised, subject to compliance with the applicable legal and regulatory provisions as set forth in Sections 7 and 13 below.

(e) Notwithstanding any other provision hereof or of this Agreement and Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof, unless allowable under applicable law.

5. Exercise Conditions. The exercise of this Stock Option is subject to:

(a) the existence of Continuous Service at the date of exercise of the said Stock Option in accordance with this Agreement and Plan (and notably Section 6 below), and

(b) the Company having obtained the marketing approval from US Food and Drug Administration (U.S. FDA) of Viaskin Peanut. This condition shall be determined by the Board of Directors (the Performance Condition).

6. Termination of Continuous Service. The exercise of the Stock Option is subject to the existence of Continuous Service at the date of exercise of the said Stock Option in accordance with this Agreement and Plan, subject to the exceptions set forth in this Section 6. If the Optionee's Continuous Service is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.

(a) Termination Due to Death. If the Optionee's Continuous Service terminates by reason of the Optionee's death, any portion of this Stock Option shall be fully vested, and may thereafter be exercised (subject to completion of the Performance Condition at the date of exercise) by the Optionee's heir(s) for a period of six (6) months from the date of death, even if such date falls after the Expiration Date.

(b) Termination Due to Disability. If the Optionee's Continuous Service terminates by reason of the Optionee's Disability, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may thereafter be exercised by the Optionee (subject to completion of the Performance Condition at the date of exercise) for a period of six months from the date of Disability or until the Expiration Date, if earlier. Any portion of this Stock Option that is not vested on the date of Disability shall terminate immediately and be of no further force or effect.

(c) Termination for Cause. If the Optionee's Continuous Service terminates for Cause, any portion of this Stock Option outstanding on such termination date according to the vesting schedule set forth in Section 2, to the extent exercisable on such termination date, shall terminate immediately and be of no further force and effect. Any portion of this Stock Option that is not vested on such termination date shall also terminate immediately and be of no further force and effect.

(d) Retirement. If the Optionee's Continuous Service terminates as a result of Retirement, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may thereafter be exercised (subject to completion of the Performance Condition) by the Optionee at any time before the Expiration Date of the Stock Option. Any portion of this Stock Option that is not vested on the date of Retirement shall continue to vest in accordance with the vesting schedule set forth in Section 2 and become exercisable after attainment of vesting (subject to completion of the Performance Condition) at any time before the Expiration Date of the Stock Option.

(e) Other Termination. If the Optionee's Continuous Service terminates for any reason (including a termination further to a Takeover) other than the Optionee's death, the Optionee's Disability, the Optionee's Termination for Cause or the Optionee's Retirement, any portion of this Stock Option outstanding on such date according to the vesting schedule set forth in Section 2 may be exercised, to the extent exercisable on the date of termination (subject to completion of the Performance Condition), for a period of (i) ninety (90) days from the date of termination if the Optionee is a U.S. employee of a Group Company or (ii) six (6) months from the date of termination for Optionee other than U.S. employee of a Group Company, or until the Expiration Date, if earlier. Any portion of this Stock Option that is not vested on the date of termination shall terminate immediately and be of no further force or effect.

For the avoidance of doubt, the date of termination of the Optionee's Continuous Service shall be as follows, it being specified that such date of termination may be adapted from time to time depending on any local applicable laws:

- in the event of death or Disability, the date of such Optionee's death or determination of Disability;
- in the event of resignation of the contract of employment or the corporate mandate, with effect from the day that the Group Company receives the letter of resignation from the Optionee or the day that it is handed to an authorized representative of the Group Company;
- in the event of dismissal, with effect from the day that the relevant party receives the dismissal notification letter, notwithstanding (i) a notice period, whether or not completed; (ii) any challenge by the Optionee to their dismissal and/or the reasons for it; and (iii) any legal ruling that would challenge the grounds for the dismissal;
- in the event of contractual termination, with effect from the administrative approval of the termination agreement;
- in the event of the revocation of the corporate mandate, with effect from the day of the meeting of the executive body deciding on its revocation if the Optionee is in attendance, or, if he is not in attendance, from the date that notification of this decision is received, notwithstanding (i) a notice period, whether or not completed; (ii) any challenge by the Optionee to the revocation and/or the reasons for it; and (iii) any legal decision that would challenge the validity of the revocation;
- in the event of the non-renewal of the corporate mandate, with effect from the expiry date of the corporate mandate.

If the Optionee is a U.S. employee of a Group Company, the date of termination shall be as follows:

- in the event of death or Disability, the date of such Optionee's death or determination of Disability by the Company Group or its designee;
- in the event of resignation (or equivalent) by the Optionee, the date specified in any letter of resignation by the Optionee or such as earlier date as determined in its sole discretion by the Group Company in which the Optionee holds an employee or Director position at the date of termination;

- in the event of termination (dismissal, removal or equivalent) of the Optionee's Continuous Service by the Group Company in which the Optionee holds an employee or Director position, the date specified by such Group Company;
- in the event that there is a contract of employment or a corporate mandate bewteen the Optionee and the Group Company in which the Optionee holds an employee or Director position, the date specified in such contract of employment or contract mandate for the relevant type of termination or as mutually agreed by the parties; or
- in the event of agreed termination (or equivalent), the date of execution of the termination agreement by all parties.

The Board's determination of the reason for termination of the Optionee's Continuous Service shall be conclusive and binding on the Optionee and his or her legal heirs.

7. Suspension of Exercise Rights.

(a) Notwithstanding anything in this Agreement and Plan, this Stock Option may not be exercised (i) for a period of 30 calendar days prior to the publication of the annual and half-yearly results, (ii) for a period of 15 calendar days prior to the publication of the quarterly revenue figures or (iii) when Optionee holds "inside information." For this purpose, "inside information" is any information which, if made public, could have a significant influence on the price determined in accordance with 7.1 of the Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse.

(b) In addition, the Board may also elect to temporarily suspend the right to exercise this Stock Option, upon occurence of certain financial transactions involving the share capital of the Company and which require accurate prior knowledge of the number of issued shares composing the share capital of the Company. In such event, Optionee will be informed by letter of the date on which exercise is suspended and the date of resumption. This information shall be provided by non-recorded delivery, with seven days' advance notice.

(c) If the event the Optionee's Continuous Service terminates during any exercise suspension period, Optionee may exercise this Stock Option at the end of the suspension period (to the extent then exercisable and subject to completion of the Performance Condition) for an additional period that is equal to the term of the suspension (or if earlier, through the Expiration Date), without this period extending the initial term of validity of the Stock Option.

8. Transferability. This Stock Option is not transferable and non-assignable as provided for in Article L.225-183 of the French Code, subject to the provisions of Section 6 (a) above.

9. Tax Withholding Obligations.

(a) At the time this Stock Option is exercised, in whole or in part, and at any time thereafter as requested by the Company, Optionee hereby authorizes withholding from payroll and any other amounts payable to Optionee, and otherwise agrees to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or a Subsidiary, if any, which arise in connection with the exercise of this Stock Option.

(b) Optionee may not exercise this Stock Option unless the tax withholding obligations of the Company and/or any Subsidiary are satisfied. Accordingly, Optionee may not be able to exercise this Stock Option when desired even though the option is vested, and the Company will have no obligation to issue a certificate for such Shares or otherwise enter Optionee's name as the stockholder of record on the books of the Company, unless such obligations are satisfied.

(c) Optionee hereby agrees that the Company does not have a duty to design or administer this Agreement and Plan or its other compensation programs in a manner that minimizes Optionee's tax liabilities. Optionee will not make any claim against the Company, or any of its officers, directors, employees, Subsidiaries or affiliates related to tax liabilities arising from this Stock Option or Optionee's other compensation and the Company encourages the Optionee to consult at his/her own expenses with his/her own tax adviser to determine the tax consequences applicable to him/her in relation to this Stock Option. In particular, in the event the Optionee is a US tax resident, Optionee acknowledges that this option is exempt from Section 409A of the Code only if the exercise price per share is at least equal to the "fair market value" per Share on the Grant Date and there is no other impermissible deferral of compensation associated with the option.

10. Adjustments for Changes in Capitalization. In the case of an event described in Article L.225-181 of the French Code, the Company shall take the necessary action to protect the interests of the Optionee beneficiaries under the conditions stipulated in Article L.228-99 of the French Code. For this purpose, the Company will take all the measures stipulated in Article L.228-99 of the French Code. In particular, it may adjust the number of Shares subject to this Stock Option and the Option Exercise Price under the conditions and following the procedures laid down by the regulatory provisions of the French Code for each scenario that qualifies for an adjustment. The Board's adjustments shall be final, binding and conclusive.

11. No Obligation to Continue Service. Neither the Company nor any Subsidiary is obligated by or as a result of this Agreement and Plan to continue the Optionee's Continuous Service and this Agreement and Plan shall not interfere in any way with the right of the Company or any subsidiary to terminate the employment or other service of the Optionee at any time or for any reason.

12. Data Privacy. In order to administer this Agreement and Plan and to implement or structure future equity grants, the Company, its Subsidiaries and affiliates and certain agents thereof (together, the "***Relevant Companies***") may process any and all personal or professional data, including but not limited to any identification number (excluding the social security number), home address and telephone number, date of birth and other information that is necessary or desirable for the administration of this Agreement and (the "***Relevant Information***"). By entering into this Agreement and Plan, the Optionee acknowledges being informed (i) of the legitimate interest of the Company to collect, process, register and disclose to the Relevant Companies all Relevant Information; (ii) that the Relevant Companies may store and transmit such information in electronic form; and (iii) that the Relevant Information may be transferred to any jurisdiction in

which the Relevant Companies consider appropriate, being specified that where the concerned jurisdiction is not located within the European Union, the Company undertakes to take all relevant guarantees, either on the basis of an adequacy decision or, in the absence of such a decision, on the basis of appropriate safeguards (e.g. binding corporate rules or contractual clauses), whose copy can be made available upon request. The Relevant Information will be stored only for the required duration for the purposes of administering this Agreement and Plan and implementing or structuring future equity grants as well as, beyond, for the purposes of evidence and legal obligations for a period not exceeding the applicable statutory limitation periods. The Optionee shall have access to, and the right to change, delete, if any limit or object, subject to legitimate and compelling reasons, the Relevant Information. These rights can be exercised directly by notifying the Company under the conditions stated in Section 17 below.

13. Trading Policy Restrictions.

(a) Exercise of this Stock Option and the disposition of any Shares issued in connection therewith shall be subject to the Company's insider trading policies and procedures, and all applicable laws regarding insider trading, restriction on exercise and sale of the Shares as in effect and applicable to Optionee from time to time. In addition, Optionee acknowledges receipt of the Company's policy permitting certain individuals to sell shares and exercise options only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

(b) In accordance with the provisions of Article L.621-18-2 of the French Monetary and Financial Code, the exercise of this Stock Option and the disposition of any Shares issued in connection therewith by a corporate officer or any person who has, within the Company, (i) the power to take management decisions regarding its development and strategy, (ii) regular access to inside information relating directly or indirectly to the Company, requires that the French *Autorité des Marchés Financiers* be informed, with a copy sent to the Company, within the timeframe laid down in the regulations currently in force (currently within five (5) trading days).

14. Claw Back. For US employees, any amounts paid (or shares of Common Stock granted) under this Stock Option will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any plan of or agreement with the Company.

15. Governing Law. This Agreement and Plan are subject to and must be interpreted according to the provisions of French law and any dispute relating thereto will fall under the exclusive competence of the court with appellate jurisdiction for the location of the Company's registered office.

16. Certain Definitions.

(a) "***Board***" means the Board of Directors of the Company, or as context requires, the group then responsible for administration of this Stock Option and/ this Agreement and Plan at the relevant time (i.e., either the Board or a committee or committees of the Board, as applicable) or delegated relevant administrative authority with respect to this Agreement and Plan and/or this Stock Option.

(b) "***Cause***" shall mean, unless otherwise provided in an employment agreement between a Group Company and the Optionee, as determination by the Group Company to dismiss the Optionee as a result of the Optionee's gross negligence or willful misconduct. Such definition may be adapted from time to time depending on any local applicable laws defining "cause" in terms comparable to Cause.

For the sake of clarity, it is specified that for:

- U.S. employees, "Cause" shall mean, (i) the Optionee's dishonest statements or acts with respect to the Company or any Subsidiary or affiliate of the Company, or any of the Company or any Subsidiary's current or prospective customers, suppliers vendors or other third parties with which such entity does business; (ii) the Optionee's commission of (A) a felony or (B) any misdemeanor involving moral turpitude, deceit, dishonesty or fraud; (iii) the Optionee's gross negligence or willful misconduct with respect to the Company or any Subsidiary or affiliate of the Company; or (iv) the Optionee's material violation of any provision of any agreement(s) between the Optionee and the Company (or any Subsidiary of the Company) relating to noncompetition, nondisclosure and/or assignment of inventions;
- French employee, "Cause" shall mean the Optionee's **(i)** gross negligence *"faute grave"* as this notion is determined by the labor division of the French *Cour de cassation* or **(ii)** willful misconduct "*faute lourde"* as this notion is determined by the labor division of the French *Cour de cassation*.

(c) "***Code***" means the U.S. Internal Revenue Code of 1986, as amended.

(d) "***Continuous Service***" means that the Optionee's service with a Group Company, whether as an employee or Director, is not interrupted or terminated. A change in the capacity in which the Optionee renders service to a Group Company as an employee or Director or a change in the entity for which the Optionee renders such service, provided that there is no interruption or termination of the Optionee's service with the a Group Company, will not terminate the Optionee's Continuous Service; *provided, however,* that if the entity for which the Optionee is rendering services ceases to qualify as a Group Company, as determined by the Board, in its sole discretion, the Optionee's Continuous Service will be considered to have terminated on the date such entity ceases to qualify as a Group Company. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, a Subsidiary, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to

the Optionee, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A of the Code, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of "separation from service" as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(e) "**Director**" shall mean a member of the Board of Directors of the Company.

(f) "***Disability***" means the inability of the Optionee to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances. Such definition may be adapted from time to time depending on any local applicable laws defining "disability" in terms comparable to Disability.

For the sake of clarity, it is specified that for **(i)** U.S. employees, Disability shall have the meaning ascribed to it in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code or as determined under any applicable company long-term disability plan and **(ii)** French employees, Disability shall have the meaning ascribed to it in Article L.341.4 of the French Social Security Code.

(g) "***Group***" means the Company and its Subsidiaries.

(h) "***Group Company***" means a company of the Group.

(i) "***Retirement***" means (i), if the Optionee is a U.S. employee of a Group Company, termination of Continuous Service after attainment of age 62 or (ii), in respect of Optionee other than U.S. employee of a Group Company, termination of Continuous Service due to retirement as decided by the Optionee or by the Group Company as provided for under any applicable law.

(j) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50 percent of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50 percent.

(k) "***Takeover***" has the meaning provided in Article L.233-3 of the French Code. Such definition may be adapted from time to time depending on any local applicable laws defining "takeover" in terms comparable to Takeover. For the avoidance of doubt, it is specified that a Takeover for a U.S. Optionee also complies with the definition of "change of control" under Section 409A of the Code.

17. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Optionee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing. The Company may, in its sole discretion, decide to deliver any documents related to participation in this Agreement and Plan and this Stock Option by electronic means or to request the Optionee's consent to participate in this Agreement and Plan by electronic means. By accepting this Stock Option, the Optionee consent to receive such documents by electronic delivery and to participate hereunder through an on-line or electronic system established and maintained by the Company or another third party designated by the Company from time-to-time.

**Exhibit 4.18**

**2018 FREE SHARE PLAN**

**REGULATION**

**TABLE OF CONTENTS**



**2018 FREE SHARE PLAN**

**REGULATION 2018**

Based on the authorization granted by the combined general meeting on June 22, 2018 the Board of Directors of DBV Technologies (the "**Company**") decided, at its meeting on June 22,2018 in accordance with Articles L.225-197-1 to L.225-197-5 of the Commercial Code, to adopt a regulation ("**2018 FREE SHARE Regulation**") for the purpose of awarding free shares in the Company to Eligible Persons (as defined below), which bylaw will govern the awarding of free shares, and the terms and conditions of which are set out below.

**1. DEFINITIONS**

(a) "**Share**" means a share of the Company;

(b) "**Free Share Allocation**" means the free share allocation on the terms and conditions set out in Regulation 2018;

(c) "**Shareholders' Authorization**" means the authorization to allocate shares free of charge granted to the Board of Directors by the shareholders of the Company at the extraordinary combined general meeting on June 22, 2018;

(d) "**Beneficiary**" means an Eligible Person to whom at least one Share has been allocated free of charge in accordance with Regulation 2018;

(e) "**Change of Control**" means the completion of any transaction that has the effect of bringing about a change in the Control of the Company. The term *"Control"* has the meaning given to it in Article L.233-3 of the Commercial Code;

(f) "**Award Date**" means the date on which the Board of Directors grants the Free Share Allocation and constitutes the date on which the Acquisition Period commences;

(g) "**Eligible Person**" means an officer (President, director general, or deputy director general of the Company) or employee of the Company or an Affiliate Company who meets the conditions set out in Articles L.225-197-1 and L.225-197-2 of the Commercial Code and satisfies the conditions and criteria for the award established by the Board of Directors in its decision of June 22, 2018 and set out in Article 7 of Regulation 2018;

(h) "**Manager**" means the Board of Directors of the Company that administers Regulation 2018 in accordance with Article 3 of Regulation 2018;

(i) "**Disability**" means a disability on the part of the Beneficiary that corresponds to classification in the second or third category provided in Article L.341-4 of the Social Security Code;

(J) "**Regulation 2018**" means this 2018 Free Share Plan as adopted by the Manager on June 22, 2018.

(k) "**Employee**" means a natural person who is employed by the Company (or any Affiliated Company) and is subject to the power of control and direction of the employer entity in the performance and conduct of the work to be carried out;

(l) "**Company**" means DBV Technologies, a limited company incorporated under French law;

(m) "**Affiliated Company**" means a company that meets the criteria set out in Article L.225-197-2 of the Commercial Code:

- companies of which at least ten percent (10%) of the capital or voting rights are held, directly or indirectly, by the Company;
- companies that hold, directly or indirectly, at least ten percent (10%) of the capital or voting rights of the Company; and
- companies of which at least fifty percent (50%) of the capital or voting rights are held, directly or indirectly, by a company that itself holds, directly or indirectly, at least fifty percent (50%) of the capital or voting rights of the Company.

## 2. SHARES COVERED BY REGULATION 2018

All Free shares plan based on the authorization granted by the combined general meeting on June 22, 2018 to the Board of Directors of DBV Technologies.

The total number of Free shares according with the Shareholder's authorization shall not exceed 4.5% of the share capital on the date of June 22, 2018, Meeting (i.e. 1,350,285 shares).

## 3. ADMINISTRATION OF REGULATION 2018

### (a) Administration

Regulation 2018 will be administered by the Manager.

**(b) Powers of the Manager**

Within the limits of the Commercial Code, the Shareholders' Authorization and Regulation 2018, the Manager will have discretion to:

i. determine the Eligible Persons to whom Shares will be allocated free of charge and decide the number of bonus Shares to be awarded to each of them;

ii. determine the terms and conditions of any Free Share Allocation;

iii. analyze and interpret the terms of Regulation 2018;

iv. decide to change or cancel any rule in Regulation 2018, within the limits prescribed by law;

v. make any necessary or advisable decision in the course of executing Regulation 2018.

**(c) Effects of Decisions of the Manager**

The decisions and interpretations of the Manager are final and binding on all Beneficiaries.

## 4. LIMITATIONS

**(a)** The Shares allocated free of charge are governed by Articles L.225-197-1 to L.225-197-5 of the Commercial Code. They do not in any way constitute a component of the contract of employment or office or compensation of the Beneficiary.

Neither Regulation 2018 nor any Share allocated free of charge confers a right on the Beneficiary to remain in employment in the Company or an Affiliated Company, or in office in the Company. Moreover, they do not in any event limit the right that the Beneficiary, the Company, or an Affiliated Company, as the case may be, may have to terminate such employment or office in any circumstance, with or without cause.

**(b)** In accordance with Article L.225-197-1 of the Commercial Code, no Share may be allocated free of charge to an Eligible Person who, at the time of allocation the Share, directly holds more than 10% of the capital of the Company, or for whom the effect of the award would be to increase his/her participation to more than 10% of the capital of the Company.

## 5. TERM OF REGULATION 2018

Relying on the authorization and powers granted to it by the General Shareholders' Meeting on June 22, 2018, the Board of Directors, in its decision dated June 22, 2018 decided to adopt Regulation 2018, which came into effect on June 22, 2018. Unless it is cancelled early in accordance with the provisions of Article 11, Regulation 2018 will remain in effect until the expiration of the Retention Period for the last Share allocated free of charge.

## 6. BONUS SHARE AWARD

### (a) Decision to award

The Manager will decide during Board of Directors meetings to allocate free shares to the new DBV Technologies S.A.'s employees according a fixed ratio.

### (b) Award of Shares and Acceptance by Beneficiaries

Each Eligible Person will be informed of the Free Share Allocation by a notification letter setting out, in particular, (i) the number of Shares allocated free of charge to him/her, (ii) the term of the Acquisition Period, (iii) the term of the Retention Period, (iv) the conditions and criteria to be met in order for the award to become definitive at the end of the Acquisition Period, and (v) any obligation imposed on him/her. A copy of Regulation 2018 will be attached to the notification letter. A sample notification letter is set out in an Appendix to Regulation 2018.

The notification letter will be sent to the Beneficiary by registered mail with acknowledgement of receipt or delivered by hand to the Beneficiary by the Manager or by any duly authorized person, and the Beneficiary will acknowledge receipt.

In the event that the Beneficiary would like to take up the Free Share Allocation, he/she must make his/her acceptance known to the Company by sending the second copy of the notification of the Free Share Allocation to the Company, addressed to the Manager, by registered mail with acknowledgement of receipt or by hand, signed by him/her under the notation "*Good for acceptance,*" within thirty (30) days of receipt of the notification of the Free Share Allocation.

Acceptance of Regulation 2018 by a Beneficiary constitutes acceptance of all of its terms.

## 7. CRITERIA AND CONDITIONS OF AWARD

The Share award presumes that each Beneficiary meets the following conditions and criteria, which were decided General Shareholders' Meeting on June 22, 2018 and by the Board of Directors in its decision dated June 22, 2018, and which have been brought to the attention of the Beneficiaries by individual letter:

- the Beneficiary must continue to be an Eligible Person throughout the entire Acquisition Period.
- The definitive allocation of the free shares will only occur at the later of the following two dates, subject to the presence requirement set out below:

  (i) expiry of the current vesting period as from their initial allocation; and

  (ii) approval of Viaskin Peanut by the US Food and Drug Administration (US FDA) (performance condition).

## 8. CALENDAR FOR THE BONUS SHARE AWARD

### (a) Acquisition Period

The Free Share Allocation to Beneficiaries will become definitive only at the end of an Acquisition Period of a minimum of one (1) year from the allocation date, or, on the terms set out in Article 7, on the condition that, throughout the entire Acquisition Period, the Beneficiary has continued to be an Eligible Person.

In accordance with Article L.225-197-3 of the Commercial Code, the rights resulting from the Free Share Allocation may not be assigned or transferred by any method whatsoever until the end of the Acquisition Period. However, in the event of the death of the beneficiary, his/her heirs may request that the shares be awarded within six months from the date of death.

The definitive award is subject to an attendance requirement that is determined in accordance with the precise terms and conditions below. In order to be Eligible, beneficiaries must therefore have a relationship with the Company or an Affiliated Company, throughout the entire Acquisition Period, by virtue of an office and/or a contract of employment.

Accordingly, in the event of resignation, voluntary or involuntary retirement, termination of the Beneficiary's contract of employment by mutual agreement with the company concerned, dismissal, removal, or non-renewal of the Beneficiary's office, during the Acquisition Period, for any cause whatsoever, the Beneficiary would, unless otherwise first decided by the Manager, lose all rights to the Free Share Allocation and could make no claim for compensation in that regard.

- **Dismissal of the Beneficiary and/or removal and/or non-renewal of the Beneficiary's offices during the Acquisition Period:**
    - **If the Beneficiary has only a contract of employment**, the loss of the right to the Free Share Allocation will take place on the date of receipt (or first presentation) of the letter of notification of dismissal, notwithstanding (i) any notice requirement, whether or not it has been given; (ii) any dispute by the beneficiary of his/her dismissal and/or the reasons for the dismissal, and (iii) any judicial decision setting aside the dismissal.
    - **If the Beneficiary has only an office**, the loss of the right to the Free Share Allocation will take place on the date of the meeting of the corporate body at which the removal was decided or the Beneficiary was replaced as the office holder, if the beneficiary is a member of it, and if the Beneficiary is not a member of it, as of the date on which notice of the decision is received by the Beneficiary, notwithstanding (i) any notice requirement, whether or not it has been given; (ii) any dispute by the beneficiary of his/her removal and/or the reasons for the removal, and (iii) any judicial decision setting aside the removal.
    - **If the Beneficiary has both a contract of employment and an office and, in the event of the simultaneous or successive loss of both positions**, the loss of the right to the Free Share Allocation will take place on the date of receipt of the latter of the two notices referred to in the two preceding paragraphs.
- **Resignation during the Acquisition Period:**

In the event of the resignation of the Beneficiary from his/her position as an employee, if the Beneficiary is an employee only, or as an officer, if the Beneficiary is an officer only, or in the event of simultaneous or successive resignation from his/her position as an employee and as an officer, in the event that the Beneficiary holds both positions at the same time, the loss of the right to the Free Share Allocation will take place:

- **if the Beneficiary is only an employee or an officer**, on the date of receipt by the Company of the Beneficiary's letter of resignation or on the date on which it is delivered by hand to an authorized representative of the Company that employs him/her; and

- **if the Beneficiary holds positions as both an employee and an officer**, the date of receipt by the Company of the first of the letters of resignation, or the date on which it is delivered by hand to an authorized representative of the Company that employs him/her.

notwithstanding any notice requirement, whether or not it has been given.

- **Mutual agreement between the Beneficiary and the company that employs him/her during the Acquisition Period:**

In the event of termination of the contract of employment by mutual agreement between the Beneficiary and the company that employs him/her (including in the case of contractual termination) if the Beneficiary is only an employee, or in the case of termination of the contract of employment by mutual agreement between the Beneficiary and the company that employs him/her and the simultaneous or successive resignation or removal from his/her office, in the event that the Beneficiary holds both positions at the same time, the Beneficiary would lose his/her right to the Free Share Allocation on the first date on which the agreement terminating the Beneficiary's position as an employee is signed (or on which the agreement relating to the contractual termination is made), or the date of receipt of the notification of removal from office or the date of resignation from office.

- **Retirement of the Beneficiary during the Acquisition Period;**

In the event that the Beneficiary retires during the Acquisition Period, the Beneficiary will lose his/her right to the Free Share Allocation on the date of retirement.

However, by exception to the foregoing:

(i) in the event of the involuntary retirement of the Beneficiary at the initiative of the company that employs him/her during the Acquisition Period, in accordance with the applicable statutory and regulatory requirements, the Beneficiary will retain his/her right to the Free Share Allocation, on the condition that he/she adheres to the Acquisition Period;

(ii) in the event of the death of the Beneficiary during the Acquisition Period, his/her heirs may request the Free Share Allocation within six (6) months of the death;

(iii) in the event of disability, the Beneficiary may request that the Shares be awarded within six (6) months of the event that resulted in the disability.

It is specified that during the Acquisition Period, the Beneficiaries are not the owners of the Shares and have no shareholder's rights. In particular, they do not have the right to dividends, the right to vote, or the right to the information communicated to shareholders attached to the Shares.

**(b) Delivery of the Shares**

At the end of the Acquisition Period, the Company will, on the condition that the Beneficiary has adhered to the conditions and criteria of acquisition set out in Article 7 above, transfer to the Beneficiary the number of Shares decided by the Board of Directors.

The shares awarded will immediately be treated in the same manner as the existing shares and will carry immediate dividend rights.

**(c) Share Retention Period**

The Shares must be retained by the Beneficiary throughout the Retention Period. As an exception, the shares will be freely transferable in the event of the death or disability of the Beneficiary.

If the Beneficiary is an officer, he/she will be required to administer at least 10% of the Shares awarded to him/her as registered shares until he/she ceases to hold office.

The Shares must be held in registered form in an account specifying that they are not available.

The Beneficiary has standing as a shareholder when the Shares are definitively awarded and throughout the Retention Period and may therefore exercise the rights attached to the bonus Shares throughout the Retention Period.

At the end of the Retention Period, the Shares may be freely transferred by the Beneficiary, subject to the provisions of the Company's articles of association and the regulations applicable to companies whose shares are listed on a regulated market.

## 9. ADJUSTMENTS

The Manager will be the only person with authority to decide, where applicable, the conditions on which the number of bonus Shares awarded will be adjusted in the event of transactions involving the capital of the Company in order to preserve the rights of the Beneficiaries of the said Free Share Allocations.

## 10. INTERVENING TRANSACTIONS

### (a) Take over of control

In the event of a takeover of control and by derogation from the provisions of Articles 7 and 8 of this regulation, the beneficiaries will remain eligible for the allocation at the end of the vesting period, even if their employment contract and/or corporate mandate is terminated, for any reason, between the date of the takeover and the last day of the vesting period. In this specific case, the shares will vest with no requirement to wait for the plan's performance criteria to be met.

### (b) Exchange of Shares

In the event of an exchange of shares resulting from a merger or split carried out in accordance with the regulations in force during the acquisition period, the provisions of this Article and, in particular, the above-mentioned periods, for the times remaining to run on the date of the exchange, will continue to be applicable to the rights to the award and the shares received in exchange.

## 11. AMENDMENT OF REGULATION 2018—MANAGEMENT

### (a) Amendment

The Manager may, at any time, amend the provisions of, suspend, or terminate Regulation 2018, on the condition that it is done in compliance with the law.

### (b) Consequences of Amendment or Cancellation

No amendment, alteration, suspension, or cancellation of Regulation 2018 may reduce the rights of a Beneficiary without his/her agreement, unless such amendment results from a legislative or regulatory provision that has newly come into force or from any other provision that has executory effect and is mandatory for the Company or an Affiliated Company.

### (c) Management

The management of Regulation 2018 is assigned to the Manager. However, the Manager reserves the ability to assign the management of Regulation 2018 to any financial institution. The Manager will inform the Beneficiaries by registered letter with acknowledgement of receipt or delivery by hand specifying the name and contact information of the financial institution chosen by the Manager to handle the management of Regulation 2018.

## 12. TAX AND SOCIAL SECURITY RULES

The Beneficiary will bear the cost of all taxes and mandatory deductions for which he/she is responsible under the tax regulations in force on the date on which the taxes or deductions become payable.

The Beneficiary is invited to obtain advice about his/her own personal tax situation, in particular in order to be aware of the tax and social security treatment that will apply to him/her, and the Beneficiary declares that he/she is not in any way relying on any tax or social security advice given by the Company.

## 13. SPECIFIC RESTRICTIONS AND INFORMATION

Any person who holds shares of a company must, in general, abstain from transferring them, acquiring new shares, or giving advice concerning those shares if he/she is in possession of information that could have a significant influence on the market price of the company that has not been made public. Persons who violate those rules may be subject to penal and financial sanctions. Those rules apply to Eligible Persons who receive Shares.

We invite you to refer to the Code of Ethics adopted by the Company that is online on the Intranet.

Moreover, in accordance with Article L.225-197-1 I of the Commercial Code, the Shares may not be assigned or transferred after the expiration of the Retention Period:

- within ten (10) trading sessions preceding and three (3) trading sessions following the date on which the consolidated accounts or, if none, the annual accounts are made public;
- within the time between the date on which the corporate bodies of the Company have knowledge of information that, if it were made public, could have a significant impact on the market price of the Company's shares, and the date ten (10) trading sessions before the date on which the information is made public.

A calendar of publications is distributed annually and is accessible online on the Intranet.

In accordance with the provisions of Article L.621-18-2 of the Monetary and Financial Code, the transfer of shares by an officer or any person who has, within the Company, (i) the power to make management decisions concerning the Company's activities and strategy, and (ii) regular access to privileged information concerning the Company directly or indirectly requires that information be provided to the Autorité des Marchés Financiers [financial markets authority], with a copy to the Company, within the time allowed by the regulations in force.

## 15. LIABILITY OF THE COMPANY

The Company and its Affiliated Companies may not, in any way, be held liable if, for any reason whatsoever not attributable to the Company or its Affiliated Companies, a Beneficiary was not able to acquire the Shares awarded to him/her.

## 16. APPLICABLE LAW, JURISDICTION

Regulation 2018 is governed by French law and in particular by the provisions of Articles L.225-197-1 *et seq.* of the Commercial Code.

Any dispute relating to Regulation 2018 will be within the exclusive jurisdiction of the court of competent jurisdiction subject to the jurisdiction of the court of appeal in the place in which the head office of the Company is located.

The Free Share Allocation under Regulation 2018 authorizes the Society, at any time, to ask the Beneficiary to comply with any legislative and regulatory provision governing the Shares.

* * *

*

**APPENDIX**

**SAMPLE NOTIFICATION LETTER CONCERNING DBV TECHNOLOGIES FREE SHARE ALLOCATION**

Montrouge, [date]

[Name of Beneficiary]

Dear Sir/Madam:

We are pleased to inform you that the Board of Directors of the Company has decided to allocate free shares of the Company to you in accordance with the provisions of the regulation governing the free share plan, a copy of which is attached in an Appendix ("**Regulation 2018**").

The terms that are not defined in this letter and that are capitalized have the meaning assigned to them in Regulation 2018.

These free Shares have been awarded under the provisions of Articles L.225-197-1 to L.225-197-5 of the Commercial Code.

Under the decision of the Board of Directors, you were awarded [ ] ([ ]) free shares of the Company, on [ ], on the terms set out below.

**1. Acquisition Period and conditions**

The definitive allocation of the free shares will only occur at the later of the following two dates, subject to the presence requirement set out below:

(i) expiry of the current vesting period as from their initial allocation; and

(ii) approval of Viaskin Peanut by the US Food and Drug Administration (US FDA) (performance condition).

**2. Conditions and criteria of allocation**

The Free Share Allocation assumes that during the Acquisition Period referred to above, you will meet the following conditions and criteria:

You must, throughout the Acquisition Period, have a relationship with the Company or an Affiliated Company under an office and/or a contract of employment.

In the event of resignation, voluntary or involuntary retirement, termination of the contract of employment by mutual agreement, dismissal, removal, or termination of the office, during the Acquisition Period, for any reason whatsoever, you will lose all right to the Free Share Allocation and may claim no compensation in that regard.

In the event of resignation, the loss of the right to the Free Share Allocation will occur on the date of receipt by the Company or the Affiliated Company concerned of your letter of resignation or on the date of delivery by hand of the letter to an authorized representative of the company that employs you, notwithstanding any notice requirement, whether or not it has been given.

In the event of dismissal or removal, the loss of the right to the Free Share Allocation will occur on the date of receipt (or first presentation) of the letter of notification of dismissal or removal, notwithstanding (i) any notice requirement, whether or not it has been given; (ii) any dispute by you of your dismissal and/or the reasons for the dismissal, and (iii) any judicial decision setting aside the dismissal.

However, by exception to the foregoing,

(i) in the event of retirement during the Acquisition Period, you will retain your right to the Free Share Allocation;

(ii) in the event of death during the Acquisition Period, your heirs may request the Free Share Allocation within six (6) months of the date of your death.

(iii) in the event disability during the Acquisition Period, you may request the Free Share Allocation within six (6) months of the date of your disability.

(iv) In the event of a takeover of control within the meaning of Article L. 233-3 of the French Commercial Code of DBV Technologies by any person acting alone or in concert with other persons, the beneficiaries will remain eligible for the allocation at the end of the vesting period, even if their employment contract and/or corporate mandate is terminated, for any reason, between the date of the takeover and the last day of the vesting period. In this specific case, the shares will vest with no requirement to wait for the plan's performance criteria to be met.

**3. Retention Period**

On the final allocation of the Shares, you agree to retain them during the Retention Period of two years.

Accordingly, the Shares awarded must be held in registered form in an account specifying that they are not available.

You will have the status of shareholder as of the final allocation of the Shares and throughout the Retention Period, notwithstanding the retention obligation. You may therefore, throughout the Retention Period, exercise the rights attached to the Shares allocated to you and, in particular, the right of communication, the right to participate in meetings, the right to vote, the right to dividends, and the preferential subscription right.

At the end of the above-mentioned Retention Period, the Shares will become available and may, in particular, be freely transferred (subject to the abstention periods referred to in Regulation 2018).

Your acceptance of the Free Share Allocation on the terms set out above constitutes acceptance of the terms of Bylaw 2018.

In the event that you accept the Free Share Allocation, we would appreciate it if you would sign two copies of this notification of Free Share Allocation and keep one copy and return the other to the Company by registered letter or delivered by hand in a period of 30 days from the receipt of this letter. Otherwise, the award will be void.

Sincerely yours,

Pierre-Henri Behnamou

Good for acceptance

[Name of Beneficiary]

*Encl.: Regulation 2018*

**Exhibit 8.1**

**Subsidiaries**

| Name of Subsidiary | State or Other Jurisdiction of Incorporation |
|---|---|
| DBV Technologies Inc. | Delaware |
| DBV Technologies Australia PTY Ltd. | New South Wales |
| DBV Technologies Canada Ltd. | Ontario |
| DBV Pharma S.A.S. | France |

**Exhibit 12.1**

**Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Daniel Tassé, certify that:

1. I have reviewed this annual report on Form 20-F of DBV Technologies S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 1, 2019

/s/ Daniel Tassé

Name: Daniel Tassé
Title: Chief Executive Officer
*(Principal Executive Officer)*

**Exhibit 12.2**

**Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, David Schilansky, certify that:

1. I have reviewed this annual report on Form 20-F of DBV Technologies S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 1, 2019

/s/ David Schilansky

Name: David Schilansky
Title: Deputy Chief Executive Officer
*(Principal Financial Officer)*

**Exhibit 13.1**

**Certification by the Principal Executive Officer pursuant to**
**18 U.S.C. Section 1350, as adopted pursuant to**
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of DBV Technologies S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel Tassé, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2019

/s/ Daniel Tassé

Name: Daniel Tassé
Title: Chief Executive Officer
(*Principal Executive Officer*)

**Exhibit 13.2**

**Certification by the Principal Financial Officer pursuant to**
**18 U.S.C. Section 1350, as adopted pursuant to**
**Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Annual Report of DBV Technologies S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Schilansky, Deputy Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2019

/s/ David Schilansky
Name: David Schilansky
Title: Deputy Chief Executive Officer
(*Principal Financial Officer*)

**Exhibit 15.1**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Post-effective Amendment Number 1 to Registration Statement No. 333-212708 on Form F-3 and Registration Statement No. 333-199513 on Form S-8 of our reports dated April 1, 2019, relating to the consolidated financial statements of DBV Technologies S.A. and subsidiaries (the "Company") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to going concern), and the effectiveness of the Company's internal control over financial reporting, appearing in the Annual Report on Form 20-F of the Company for the year ended December 31, 2018, and to the reference to us under the heading "Experts" in the Prospectus Supplement, which is part of this Registration Statement.

/s/ Deloitte & Associés

Paris-La Défense, France
April 1, 2019