
**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, 2014

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 001-36153

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)

Green Square-Bâtiment D

80/84 rue des Meuniers

92220 Bagneux France

(Address of principal executive offices)

Dr. Pierre-Henri Benhamou

Chairman and Chief Executive Officer

DBV Technologies S.A.

Green Square-Bâtiment D

80/84 rue des Meuniers

92220 Bagneux 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

American Depositary Shares, each representing one-half of one ordinary share, nominal value €0.10 per share

Ordinary shares, nominal value €0.10 per share*

Name of each exchange on which registered

The Nasdaq Stock Market LLC

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: 19,160,661 as of December 31, 2014

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). ☐ Yes ☒ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

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

TABLE OF CONTENTS

	PAGE
INTRODUCTION	
PART I	
Item 1. Identity of Directors, Senior Management and Advisers	4
Item 2. Offer Statistics and Expected Timetable	4
Item 3. Key Information	4
<i>A. Selected Financial Data</i>	4
<i>B. Capitalization and Indebtedness</i>	6
<i>C. Reasons for the Offer and Use of Proceeds</i>	6
<i>D. Risk Factors</i>	6
Item 4. Information on the Company	44
<i>A. History and Development of the Company</i>	44
<i>B. Business Overview</i>	45
<i>C. Organizational Structure</i>	77
<i>D. Property, Plants and Equipment</i>	77
Item 4A. Unresolved Staff Comments	77
Item 5. Operating and Financial Review and Prospects	77
<i>A. Operating Results</i>	83
<i>B. Liquidity and Capital Resources</i>	89
<i>C. Research and Development, Patents and Licenses</i>	93
<i>D. Trend Information</i>	93
<i>E. Off-Balance Sheet Arrangements</i>	93
<i>F. Tabular Disclosure of Contractual Obligations</i>	93
<i>G. Safe Harbor</i>	94
Item 6. Directors, Senior Management and Employees	94
<i>A. Directors and Senior Management</i>	94
<i>B. Compensation</i>	96
<i>C. Board Practices</i>	104
<i>D. Employees</i>	107
<i>E. Share Ownership</i>	107
Item 7. Major Shareholders and Related Party Transactions	108
<i>A. Major Shareholders</i>	108
<i>B. Related Party Transactions</i>	110
<i>C. Interests of Experts and Counsel</i>	112
Item 8. Financial Information	112
<i>A. Consolidated Statements and Other Financial Information</i>	112
<i>B. Significant Changes</i>	113

Table of Contents

Item 9.	<u>The Offer and Listing</u>	113
	<i><u>A. Offer and Listing Details</u></i>	113
	<i><u>B. Plan of Distribution</u></i>	114
	<i><u>C. Markets</u></i>	114
	<i><u>D. Selling Shareholders</u></i>	114
	<i><u>E. Dilution</u></i>	114
	<i><u>F. Expenses of the Issue</u></i>	115
Item 10.	<u>Additional Information</u>	115
	<i><u>A. Share Capital</u></i>	115
	<i><u>B. Memorandum and Articles of Association</u></i>	115
	<i><u>C. Material Contracts</u></i>	115
	<i><u>D. Exchange Controls</u></i>	115
	<i><u>E. Taxation</u></i>	115
	<i><u>F. Dividends and Paying Agents</u></i>	122
	<i><u>G. Statement by Experts</u></i>	122
	<i><u>H. Documents on Display</u></i>	122
	<i><u>I. Subsidiary Information</u></i>	123
Item 11.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	123
Item 12.	<u>Description of Securities Other than Equity Securities</u>	123
	<i><u>A. Debt Securities</u></i>	123
	<i><u>B. Warrants and Rights</u></i>	123
	<i><u>C. Other Securities</u></i>	124
	<i><u>D. American Depositary Shares</u></i>	124
 <u>PART II</u>		
Item 13.	<u>Defaults, Dividend Arrearages and Delinquencies</u>	126
Item 14.	<u>Material Modifications to the Rights of Security Holders and Use of Proceeds</u>	126
Item 15.	<u>Controls and Procedures</u>	126
Item 16A.	<u>Audit Committee Financial Expert</u>	126
Item 16B.	<u>Code of Ethics</u>	127
Item 16C.	<u>Principal Accountant Fees and Services</u>	127
Item 16D.	<u>Exemptions from the Listing Standards for Audit Committees</u>	128
Item 16E.	<u>Purchases of Equity Securities by the Issuer and Affiliated Purchasers</u>	128
Item 16F.	<u>Change in Registrant’s Certifying Accountant</u>	128
Item 16G.	<u>Corporate Governance</u>	128
Item 16H.	<u>Mine Safety Disclosure</u>	128
 <u>PART III</u>		
Item 17.	<u>Financial Statements</u>	128
Item 18.	<u>Financial Statements</u>	128
Item 19.	<u>Exhibits</u>	128

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 “Diallertest®,” “Viaskin®,” “EPIT™,” “DBV Technologies®” 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 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;
- the timing or likelihood of regulatory filings and approvals;
- 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 under the caption "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.

[Table of Contents](#)

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. Item 6. Directors, Senior Management and Employee.

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, 2012, 2013 and 2014 and selected statements of consolidated financial position data as of December 31, 2012, 2013 and 2014 from our consolidated audited financial statements included elsewhere 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:

	2012 (3)	2013 (3)	2014	
	Euro	Euro	Euro	US\$(1)
Operating income	€ 2,776,588	€ 3,826,313	€ 4,761,522	\$ 5,761,918
Operating expenses:				
Cost of goods sold	82,958	102,366	136,296	164,932
Research and development	11,499,368	17,366,538	21,143,442	25,585,679
General and administration	4,598,699	6,309,750	8,117,664	9,823,185
Total operating expenses	16,181,025	23,778,654	29,397,402	35,573,796
Operating profit (loss)	(13,404,437)	(19,952,340)	(24,635,880)	(29,811,878)
Financial profit (loss)	492,337	645,925	624,000	755,102
Net profit (loss)	€(12,912,100)	€(19,306,416)	€(24,011,880)	\$(29,056,776)
Earnings (losses) per share(2)				
Basic	€ (1.05)	€ (1.42)	€ (1.49)	\$ (1.81)
Diluted	€ (1.05)	€ (1.42)	€ (1.49)	\$ (1.81)
Number of shares used for computing				
Basic	12,326,779	13,604,687	16,086,247	16,086,247
Diluted	12,326,779	13,604,687	16,086,247	16,086,247

(1) Translated solely for convenience into dollars at the noon buying rate of €1.00=US\$1.2101 at December 31, 2014.

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

(3) The statement of consolidated income (loss) as of December 31, 2012 and 2013 corresponds to DBV Technologies SA's, as the company had no consolidated subsidiary as of this date.

[Table of Contents](#)

Statement of Financial Position Data:

	As of December 31,			
	2012 (2)	2013 (2)	2014	
	Euro	Euro	Euro	US\$(1)
Cash and cash equivalents	€38,348,130	€39,402,761	€114,583,141	\$138,657,059
Total assets	42,974,817	46,236,009	125,415,511	151,765,310
Total shareholders' equity	39,173,135	40,394,685	115,444,959	139,699,945
Trade non-current liabilities	631,592	1,607,228	4,418,902	5,347,313
Total current liabilities	3,170,090	4,234,096	5,551,650	6,718,052
Total liabilities	3,801,682	5,841,324	9,970,552	12,065,365
Total liabilities and shareholders' equity	42,974,817	46,236,009	125,415,511	151,765,310

- (1) Translated solely for convenience into dollars at the noon buying rate of €1.00=US\$1.2101 at December 31, 2014.
- (2) The statement of consolidated financial position as of December 31, 2012 and 2013 corresponds to DBV Technologies SA's, as the company had no consolidated subsidiary as of such date.

Exchange Rate Information

In this Annual Report on Form 20-F, for convenience only, we have translated certain euro amounts reflected in our financial statements as of and for the year ended December 31, 2014 into U.S. dollars at the rate of €1.00 = US\$1.2101, the noon buying rate for euros on December 31, 2014. You should not assume that, on that or on any other date, one could have converted these amounts of euros into U.S. dollars at that or any other exchange rate.

The following table sets forth, for each period indicated, the low and high exchange rates for euros expressed in U.S. dollars, the exchange rate at the end of such period and the average of such exchange rates on the last day of each month during such period, based on the noon buying rate in the City of New York for the euro. As used in this document, the term "noon buying rate" refers to the rate of exchange for the euro, expressed in U.S. dollars per euro, as certified by the Federal Reserve Bank of New York for customs purposes.

	Year Ended December 31,				
	2010	2011	2012	2013	2014
High	1.4536	1.4875	1.3463	1.3816	1.3927
Low	1.1959	1.2926	1.2062	1.2774	1.2101
Rate at end of period	1.3269	1.2973	1.3187	1.3779	1.2101
Average rate per period	1.3216	1.4002	1.2909	1.3303	1.3297

[Table of Contents](#)

The following table sets forth, for each of the last six months, the low and high exchange rates for euros expressed in U.S. dollars and the exchange rate at the end of the month based on the noon buying rate as described above.

	October 2014	November 2014	December 2014	January 2015	February 2015	March 2015
High	1.2812	1.2554	1.2504	1.2015	1.1462	1.1212
Low	1.2517	1.2394	1.2101	1.1279	1.1197	1.0524
Rate at end of period	1.2530	1.2438	1.2101	1.1290	1.1197	1.0741

On December 31, 2014, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = US\$1.2101. Unless otherwise indicated, currency translations in this Annual Report on Form 20-F reflect the December 31, 2014 exchange rate.

On April 24, 2015, the noon buying rate of the Federal Reserve Bank of New York for the euro was €1.00 = \$1.0876.

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 report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

Risks Related to Our Business and Industry

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, with the exception of the French research tax credit (*crédit d'impôt recherche*), or CIR, which is classified as other income in our statement of income (loss). We have incurred net losses in each year since our inception in 2002, including net losses of €12.9 million, €19.3 million and €24.0 million for the years ended December 31, 2012, 2013 and 2014, respectively. Although we have historically generated non-meaningful revenues through the sale of our Diallertest Milk product in France, we do not expect these sales to be a point of strategic focus for our company in the future and we may even discontinue these sales in the future. As of December 31, 2014, we had an accumulated deficit of €54.8 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, and reimbursements of research tax credit claims. 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. We have not completed pivotal clinical trials for any lead product candidates and it will be several years, if ever, before we have a product candidate ready for

[Table of Contents](#)

commercialization, if at all. 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 our product candidates 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:

- 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 regulatory and marketing approvals for our product candidates that successfully complete clinical studies;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval, especially in North America;
- 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 the ADSs to decline.

[Table of Contents](#)

We May Need To Raise 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 advance Viaskin Peanut and Viaskin Milk through clinical development.

As of December 31, 2014, our cash and cash equivalents were €114.6 million. We expect that our existing cash will be sufficient to fund our current operations until the end of 2016. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to pursue pre-clinical and clinical activities, pursue regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any 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. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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 the ADSs 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 funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

Under French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. See "Item 10. B—Memorandum and Articles of Association", our board 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 if it is not possible to fix the per share price of the shares at a level at least equal 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, referred to as the "book building" process, less a maximum discount of 5%.

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 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;
- depending on the regulatory authorities' requests, larger or longer clinical trials;
- the scope, prioritization and number of our research and development programs;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing, or contracting for, sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

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. 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 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 may pursue development of our other early-stage development programs. Our current early-stage development programs are still in the pre-clinical 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 has 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 Viaskin patch product candidates, 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 are and will continue to incur 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 after we are no longer an “emerging growth company” and/or 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 and will continue to file financial reports on an annual and semi-annual basis. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have been and continue to be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will increase our cost and expense. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expense and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

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.

[Table of Contents](#)

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 two lead Viaskin technology-based product candidates, Viaskin Peanut and Viaskin Milk, in clinical development, and our business depends almost entirely on their successful clinical development, regulatory approval and commercialization. We currently have no drug or biological product approved for sale and may never be able to develop a marketable drug or biological product. Viaskin Peanut and Viaskin Milk will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence their commercialization. Our other product candidates, such as Viaskin HDM, are still in pre-clinical 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 pre-clinical 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 studies and surveillance, 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 Biologic 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 insufficient to demonstrate that either the Viaskin Peanut's or Viaskin Milk's clinical and other benefits outweigh its safety risks;

[Table of Contents](#)

- 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 third-party manufacturers with which we contract; 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 Viaskin patch product candidates. Moreover, because our business is almost entirely dependent upon Viaskin technology, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Our Product Candidates Are Expected 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 the ADSs.

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;

[Table of Contents](#)

- 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 confirm an absence of statistically significant therapeutic effect of Viaskin Peanut in adolescents and/or adults, as observed in the ARACHILD pilot trial and our recently completed VIPES trial;
- 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 Viaskin patch product candidates 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 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 subjects who participate in our clinical trials and experience any such serious or fatal reactions. Any of the foregoing could have a material adverse effect on our business, prospects, stock price or financial condition.

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

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. The completion of trials for Viaskin Peanut, 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;

[Table of Contents](#)

- 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 approval of an investigational new drug, or IND, application from the FDA;
- obtaining institutional review board, or IRB, 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;

Table of Contents

- 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 BLA for our product candidate. If we experience delay, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed or such revenues could be reduced or fail to materialize.

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

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

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

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

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

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

We have obtained fast track designation for Viaskin Peanut, 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. 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, 6 to 11 years of age, 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 agency to review portions of the marketing application before submission of a complete application, and priority review if supported by clinical data at the time of our BLA submission.

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.

[Table of Contents](#)

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-approval studies and measures, 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, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the 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 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 for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. 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;

[Table of Contents](#)

- 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 Trials And Product Introductions. 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.

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 for peanut protein extract, an active pharmaceutical ingredient used in our Viaskin Peanut clinical trials. If such manufacturer cannot manufacture the peanut protein extract 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. If our clinical trials are delayed, our commercialization efforts may be impeded, or our costs may increase.

[Table of Contents](#)

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.

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;

[Table of Contents](#)

- 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 are working to develop a commercial-scale version of our electrospray manufacturing tool, but cannot predict or control issues that may arise with its development. These difficulties could delay the commercialization of our product candidates, reduce sales of our products, if approved, or increase our costs, any of which could harm our business.

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 of 2009, or BPCIA, was enacted as part of the 2010 enactments of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, to establish an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. "Biosimilarity" means that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency of the product. To meet the higher standard of "interchangeability," an applicant must provide sufficient information to show biosimilarity and demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Under the BPCIA, an application for a biosimilar or interchangeable product cannot be approved by the FDA until 12 years after the reference product was first licensed, and the FDA will not even accept an application for review until four years after the date of first

[Table of Contents](#)

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. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes 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 Are Dependent On A Single Exclusive Distributor For The Marketing Of Our Diallyrtest Milk Diagnostic Product. We May Discontinue Our Diallyrtest Milk Program.

In 2004, we introduced to the French market Diallyrtest Milk, the first ready-to-use patch test for detecting CMPA in young children. Diallyrtest Milk is the only product that we market to date, and is exclusively distributed in France through a distributor.

Diallyrtest Milk is currently available on the French market with a temporary exception status. Regulatory authorities are requesting a pivotal Phase III clinical trial to complete the marketing authorization file. We are examining the relevance of carrying out this clinical protocol, and are evaluating potential marketing and/or distribution relationships to market this product in Europe in the field of pediatrics. We may also elect, or may be required at the request of regulatory authorities, to stop the marketing of Diallyrtest Milk. If we were to stop the marketing of Diallyrtest Milk, or if our current or future distributors struggle to market this product in European markets, our ability to generate revenue from these product sales would be materially adversely effected. We cannot assure you that these product revenues will continue in the future and in any event we do not currently expect these product revenues to have a materially positive impact on our business and financial condition in future periods.

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, although many are in the discovery or pre-clinical stages. For example, Allergen Research Corporation is currently evaluating in Phase II clinical trials a formulation of peanut flour for oral administration intended for oral desensitization. We are aware of 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. has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp. and Selecta Biosciences Inc. and may pose a competitive risk to our products in the future.

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.

The ACA is expected to significantly impact the provision of, and payment for, health care in the United States. Various provisions of the ACA take effect over the next several years, and are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre-existing conditions, establish

[Table of Contents](#)

health insurance exchanges, and provide additional support for medical research. More recently, 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. 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.

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 four clinical trials of Viaskin Peanut and Viaskin Milk product candidates have been conducted both outside and inside of the United States in over 400 human subjects to evaluate the safety and efficacy of these product candidates for the treatment of peanut allergies and milk allergies. Adverse events observed in these clinical trials have primarily involved general disorders and administration site conditions, such as erythema, pruritus, edema, and urticaria. It is worth noting that, as a desensitization patch bringing the allergen into contact with the skin, Viaskin patch product candidates can, in severely allergic patients, cause some erythematous or eczema skin reactions, which are a source of itching and discomfort for the patient. 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;

Table of Contents

- 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 Viaskin patch product candidates in markets within and without the United States and Europe. If we commercialize Viaskin patch product candidates 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, Contractual Damages, Reputational Harm And Diminished Profits And Future Earnings.

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 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 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.

[Table of Contents](#)

- The federal civil and criminal false claims laws and civil monetary penalties laws impose criminal and civil penalties, including those from civil whistleblower or qui tam actions, against individuals or entities for 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 statutes that prohibit 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.
- 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 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 those companies or group purchasing organizations.
- Analogous state 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 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, and state 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. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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 and exclusion from government funded healthcare programs, such as Medicare and Medicaid, any of which could substantially disrupt our operations. 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 exclusions 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. These discussions have caused us to adjust certain trial protocols. Similar 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. 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.

To date, we do not have biopharmaceutical company status, or PCS, and therefore, cannot manufacture the product candidates that we develop in France. A company with premises located in France must submit an application to the French Drug and Health Products Safety Agency, or ANSM, in order to get PCS status. The ANSM grants PCS to a company upon evaluation and determination that such company's premises has adequate personnel, procedure and organization. We intend to seek PCS when our Viaskin patch product candidates have received MAA and thereby have the ability to manufacture our product candidates without contracting third parties. There are two types of PCS: (1) distributor "exploitant" status, 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.

Failure to obtain PCS status would force us to revise our strategy. First, failure to obtain manufacturer status would 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 distributor "exploitant" status was not obtained, we could not conduct a direct commercial approach to the French market and would therefore have to enter into marketing license agreements with other biopharmaceutical companies. Failure to obtain any of the two types of PCS status 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 and/or environmental allergies. In addition to the development of Viaskin Peanut and Viaskin Milk, we may pursue development of our other development programs, including Viaskin HDM. 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 development and commercialization of Viaskin Peanut and 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 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 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.

[Table of Contents](#)

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 and/or environmental 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

[Table of Contents](#)

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

[Table of Contents](#)

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

[Table of Contents](#)

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.

[Table of Contents](#)

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;

[Table of Contents](#)

- 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, Diallyrtest 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, 2014, we had 56 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 its 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, including in particular those of Pierre-Henri Benhamou, our Chairman and Chief Executive Officer and Bertrand Dupont, our Chief Technical Officer. The loss of the services of any of these individuals would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, 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 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 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.

We maintain product liability insurance coverage for our clinical trials with an €11.0 million annual aggregate coverage limit. Nevertheless, our insurance coverage may be insufficient to reimburse us for any expenses or losses we may suffer. In addition, in the

[Table of Contents](#)

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.

We Must Maintain Effective Internal Control Over Financial Reporting, And If We Are Unable To Do So, The Accuracy And Timeliness Of Our Financial Reporting May Be Adversely Affected, Which Could Have A Material Adverse Effect On Our Business, Investor Confidence And Market Price.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we assess the effectiveness of our disclosure controls and procedures semi-annually and the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's annual report on internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act, in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2015.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. We are in the process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation. This process is time-consuming, costly, and complicated. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company". We may cease to qualify as an emerging growth company as soon as December 31, 2015, as a result of which we would be required to comply with these requirements in our annual report for the year ended December 31, 2015. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company. If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, our business and reputation may be harmed and the price of the ADSs may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our ordinary shares.

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 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 €2.5 million, €3.3 million and €4.3 million as of December 31, 2012, 2013 and 2014, 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, we have received multiple conditional advances totaling €5.7 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 its 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, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption

[Table of Contents](#)

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 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.

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

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

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 the ADSs has fluctuated, and is likely to continue to fluctuate, substantially. The trading price of the ADSs 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.

Since the ADSs were sold at our public offering in October 2014 at a price of \$21.64 per share, the price per ADS has ranged as low as \$20.26 and as high as \$28.50 through April 24, 2015. The market price of the ADSs 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;
- additions or departures of key management or scientific personnel;

[Table of Contents](#)

- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- 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 the ADSs to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ADSs and may otherwise negatively affect the liquidity of the ADSs. 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 Sofinnova Capital V FPCI, entities affiliated with Bpifrance and entities affiliated with Baker Bros. Advisors LP, together beneficially own approximately 41.97% 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 the ADSs 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 the ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades the ADSs or publishes incorrect or unfavorable research about our business, the price of the ADSs 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 the ADSs, demand for the ADSs could decrease, which could cause the price of the ADSs 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 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.

[Table of Contents](#)

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with IFRS. In addition, payment of dividends may subject us to additional taxes under French law. 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 and the taxes that may become payable by us if we elect to pay a dividend. 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.

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of ordinary shares or ADSs in the public market, the trading price of the ADSs could decline significantly. As of March 24, 2015, 19,372,486 shares were eligible for sale in the public market, 6,147,285 of which shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In addition, the ordinary shares subject to outstanding options under our equity incentive plans and the 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. We have filed a registration statement with the SEC covering ordinary shares available for future issuance under our equity incentive plans. 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 the ADSs.

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

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

- under French law, a non-resident of France may have to file an administrative notice with French authorities in connection with a direct or indirect investment in us, as defined by administrative rulings; see the section of this Annual Report on Form 20-F titled “Item 10.B—Memorandum and Articles of Association”;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- 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;

[Table of Contents](#)

- 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;
- 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
- 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 66 2/3% of the votes 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. 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

[Table of Contents](#)

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 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.

We Are An "Emerging Growth Company" And Will Be Able To Avail Ourselves Of Reduced Disclosure Requirements Applicable To Emerging Growth Companies, Which Could Make Our ADSs Less Attractive To Investors.

We are an "emerging growth company," as defined in the JOBS Act, and we have taken advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those

[Table of Contents](#)

standards would otherwise apply to private companies. Some investors may find the ADSs less attractive because we rely on these exemptions and, as a result, there may be a less active trading market for the ADSs and the price of the ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of October 22, 2014, the date of our global offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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 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 expect to file financial reports on an annual and semi-annual basis, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. domestic issuers and will not be 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 will be 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 would not necessarily hold regularly scheduled meetings at which only independent directors are present. Currently, we intend to follow home country practice 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, 2015. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if more than 50% of our securities are held by U.S. residents and more than 50% of our executive officers or members of our board of directors are residents or citizens of the United States, we could lose our foreign private issuer status. As of January 15, 2015, approximately 48.2% 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 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

[Table of Contents](#)

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, in US dollars rather than euros and 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, its shareholders, its 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.”

We May Be At Risk Of Securities Class Action Litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

We Believe That We Were Classified As A Passive Foreign Investment Company For 2014, And Certain U.S. Holders Of Our ADSs May Suffer Adverse U.S. Federal Income Tax Consequences.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, U.S. holders of the ADSs may suffer adverse tax consequences, including having gains realized on the sale of the ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of the ADSs. See “Item 10.E—Taxation—Certain Material U.S. Federal Income Tax Considerations—Passive Foreign Investment Company Considerations.”

Our status as a PFIC will depend on the composition of our income and the composition and value of our assets (which, if we are not a “controlled foreign corporation” under Section 957(a) of the Code or we are publicly traded for the entire year being tested, may be determined in large part by reference to the market value of the ADSs and our ordinary shares, which may be volatile) from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our global offering in our business. Although it is not free from doubt, based on the composition of our income for our 2014 taxable year, we believe that we were a PFIC for our 2014 taxable year.

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 Green Square-Bâtiment D, 80/84 rue des Meuniers 92220 Bagneux, France, and our telephone number is +33 1 55 42 78 78. Our agent for service of process in the United States is CT Corporation System. 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, 2012, 2013 and 2014 amounted to €0.4 million, €1.4 million and €1.1 million, respectively. These capital expenditures primarily consisted of the acquisition of laboratory equipment and industrial tools, the refurbishment of our research and development laboratories, 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 continue to advance our research and development programs and grow our operations. We anticipate our capital expenditure in 2015 to be financed from the cash flows from operating activities and proceeds of our recent public offering. In a near future, these 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. We are advancing this unique technology to treat patients, including infants and children, suffering from severe food allergies, for whom safety is paramount, since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as anaphylactic shock.

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 offers 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 is safe and that it generates a strong immune response that results in tolerance towards the allergen. Our epicutaneous immunotherapy method allows us to address severe food allergies, as well as unmet medical needs in other immunotherapy indications.

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 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. 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 a safe, effective and patient-friendly therapy for food and pediatric allergy patients, for whom there are no currently approved treatments. Compared to other allergy treatment approaches, we believe the safety profile of our EPIT method carried-out via the Viaskin patch may offer significant therapeutic and ease-of-use advantages to these patient populations. 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 highly 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. These methods seem to be poorly designed for young children 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 during treatment, such as anaphylaxis, thus risking the patient's life during administration; some of these methods have been also associated with an increased risk of adverse long-term treatment effects, such as eosinophilic esophagitis. As a self-administered treatment with a good safety profile, we believe Viaskin has positioned us as the company with the most advanced clinical program in food allergies.

[Table of Contents](#)

The following table summarizes our most advanced product candidates:

PROGRAM	INDICATION	COMMERCIAL RIGHTS	DEVELOPMENT STAGE				
			DISCOVERY	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
Viaskin Peanut	Peanut Allergy	DBV Worldwide	FDA Breakthrough & Fast Track				
Viaskin Milk	Cow's Milk Protein Allergy	DBV Worldwide					
Viaskin Egg	Hen's Egg Allergy	DBV Worldwide					

We are focused on becoming the leader in discovering, developing and commercializing food allergy 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 products with the aim to address the highest unmet medical needs.

Our lead product candidate, 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 intended to expedite or facilitate the process for reviewing new drugs and biological products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. In September 2014, we announced topline results for our VIPES (Viaskin Peanut's Efficacy and Safety) Phase IIb clinical trial of Viaskin Peanut in peanut allergic patients, which was followed by a full study report presented at the 2015 AAAAI Annual Meeting in Houston, Texas. Pending consultation with the FDA in the spring of 2015, we plan to initiate our Phase III clinical trial in the last quarter of 2015 or first quarter of 2016.

Our second product candidate, Viaskin Milk, is being developed for cow's milk protein allergy, or CMPA, in the pediatric patient population. In November 2014, we initiated a 150-subject, multi-center, double-blind, placebo-controlled, randomized Phase I/II safety and efficacy clinical trial of repeated doses of Viaskin Milk in patients with Immunoglobulin E, or IgE, mediated CMPA, which we refer to as MILES (**MILK** Efficacy and Safety).

In February of 2015, we announced that our third food allergen product would address patients suffering from hen's egg allergy. Preclinical development for Viaskin Egg commenced in the first half of 2015.

We have further used our Viaskin technology platform to advance other innovative product development programs to address additional opportunities in immunology. Our other earlier stage product development programs include house dust mites allergy, eosinophilic esophagitis, pertussis boost vaccine and birch pollen allergy, none of which have resulted in a product candidate to date. We are also exploring earlier stage opportunities in respiratory syncytial virus vaccine, refractory hemophilia A, Crohn's disease, Celiac disease and type I diabetes.

We intend to commercialize our food allergy product candidates by ourselves in the United States and certain European countries. In other geographies and indications outside food allergies, we will explore selective partnerships 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 Develop and Seek Marketing Approval for Viaskin Peanut***—In September 2014, we announced that we achieved our primary endpoint in our Phase IIb trial of Viaskin Peanut called VIPES. In December 2011, we obtained fast track designation from the FDA for Viaskin Peanut, the first peanut desensitization product candidate to obtain this status. In April 2015, we obtained breakthrough therapy designation from the FDA for Viaskin Peanut in children, the first food allergy product candidate to obtain this status and which should allow us to develop a more efficient clinical developmental program with intensive interaction with the FDA. Pending consultation with regulatory agencies, we intend to conduct a Phase III clinical trial and seek marketing approval for Viaskin Peanut for treatment of peanut allergy.
- ***Advance the Development of Our Viaskin Technology Platform into Other Areas of Unmet Medical Need in Food and Pediatric Allergies***—We are advancing the clinical development of Viaskin Milk to address CMPA, which is typically the first food allergy in children and affects approximately 2% to 3% of the population in developed countries. We initiated MILES in November 2014. Preclinical development for Viaskin Egg began in the first half of 2015.
- ***Become a Fully Integrated Biopharmaceutical Company Focused on the Commercialization of our Viaskin Food Allergy Product Candidates in the United States and Other Major Markets***—We are utilizing our team’s unique food allergy expertise and knowledge to rapidly advance clinical development and approval of our product candidates. In anticipation of commercial launch, 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 allergy 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 believe that our Viaskin technology platform, for which we have worldwide commercialization rights, has the potential to support significant product opportunities beyond food allergies. We are pursuing a number of pre-clinical collaborations, which could enable us to broaden our product pipeline, including collaborations for the development of applications in the field of respiratory allergy or autoimmune disease, as well as other therapeutic fields, such as vaccines. 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

[Table of Contents](#)

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 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 Epipen, which are indicated for the emergency treatment of severe allergic reactions including sudden anaphylaxis 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 peanut or milk proteins, existing desensitization therapies cannot be routinely used due to the high risk of anaphylactic shock, especially in young children. Subcutaneous methods of desensitization have been shown to cause significant side effects. Only limited academic studies have been performed using oral immunotherapy and these studies have not demonstrated an immune reaction deemed sufficiently consistent to support a broadly applicable therapy. In some cases these therapies have been shown to trigger a high proportion of severe systemic reactions, and we believe that this has limited their pharmaceutical development.

[Table of Contents](#)

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 6 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. 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 an allergic inflammatory condition of the esophagus called eosinophilic esophagitis, or 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

Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important 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, 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.

[Table of Contents](#)

Due to these safety concerns, existing techniques are limited to children who are at least six years old. Given these limitations, it has been impossible 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.

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

For all these reasons, food allergy 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 apply and is effective. In particular, a therapeutic approach that promotes 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.

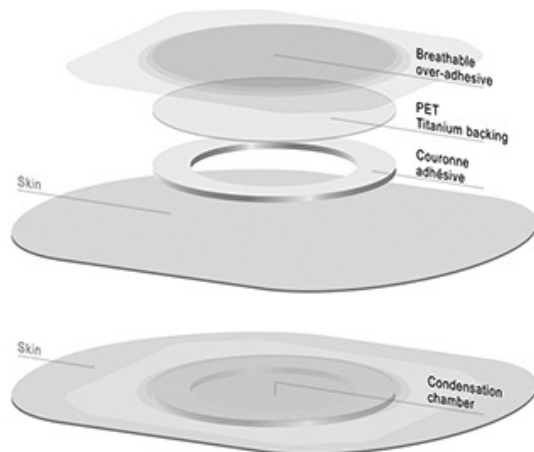
Viaskin—The First Epicutaneous Immunotherapy

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

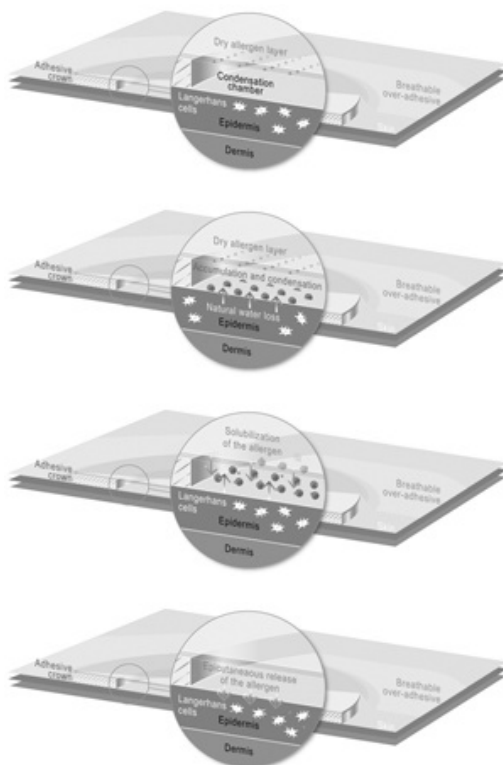
- The Viaskin patch contains the antigen in dry form, which allows it to retain its chemical properties optimally.
- The Viaskin patch creates a condensation chamber with the skin. This increases the hydration of the skin and solubilizes the antigen, which allows it to penetrate the upper layers of the epidermis. Here, the antigen is close to the most tolerogenic antigen-presenting cells in the body, Langerhans cells.
- The Viaskin patch delivers the antigen directly to the Langerhans cells, but not into the bloodstream, thereby avoiding systemic allergic reactions. This mechanism of action leads to the potential safety of Viaskin, which has been observed in multiple clinical trials in over 400 subjects.

[Table of Contents](#)

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 Epicutaneous Langerhans Cells

The 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, while barely influencing the Th1 expression.

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 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.

Viaskin—Compelling Clinical Benefits

We believe 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 safety while the activity in the lymph node explains the 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 well-demonstrated safety profile, we believe our Viaskin technology will allow for the treatment of all patients suffering from severe allergies, including very young children, without risk of 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 that the 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 allergies in children, adolescents and adults. In September 2014 we announced topline results from our VIPES trial, a multi-center, double-blind, placebo-controlled, randomized Phase IIb clinical trial of Viaskin Peanut, which was followed by a full study report presented at the 2015 AAAAI Annual Meeting in Houston, Texas. The trial met its primary endpoint at the highest explored dose (Viaskin Peanut 250 µg), achieving statistical significance ($p < 0.01$) in the percentage of treatment responders versus placebo. Our VIPES trial is the largest clinical trial in peanut allergy desensitization ever completed. In June 2013, the Assistance Publique—Hôpitaux de Paris, or AP-HP, presented data from its ARACHILD pilot trial of Viaskin Peanut. In June 2012, we presented proof-of-concept data at the European Academy of Allergy and Clinical Immunology, or EAACI, Congress from a multi-center, double-blind, placebo-controlled, randomized Phase Ib clinical trial of Viaskin Peanut.

[Table of Contents](#)

Our second product candidate, Viaskin Milk, is being developed for children (including infants) for the treatment of two indications, CMPA and milk-induced EoE. Proof-of-concept data from a pilot clinical trial of Viaskin Milk was published in *The Journal of Allergy and Clinical Immunology* in 2010. In November 2014, we initiated our MILES trial, a multi-center, double-blind, placebo-controlled, randomized Phase I/II safety and efficacy clinical trial of Viaskin Milk in the pediatric patient population with CMPA. In the first half of 2015, with our assistance, the Children's Hospital of Philadelphia intends to initiate a multi-center, double-blind, placebo-controlled, randomized trial to study safety and efficacy of Viaskin Milk in pediatric patient populations with milk-induced EoE.

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.

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 essential, as even trace amounts of peanut can cause a severe allergic reactions. According to recent studies, food allergies, mainly 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 *The Journal of Allergy and Clinical Immunology*, 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.

Development Program for Viaskin Peanut

Phase IIb Clinical Trials—VIPES and VIPES OLFUS

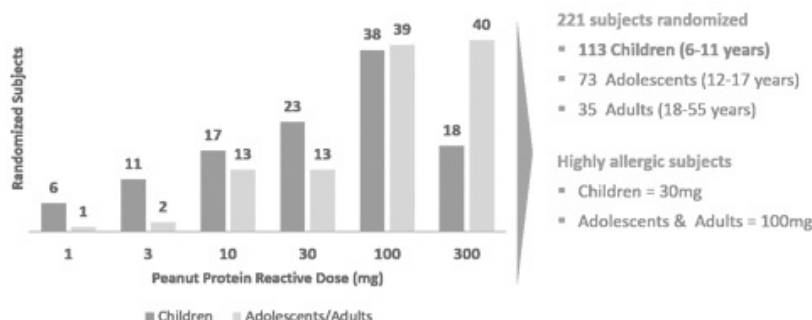
VIPES (Viaskin Peanut's Efficacy and Safety)

In August 2012, we initiated VIPES, a double-blind, placebo-controlled, multi-center Phase IIb clinical trial of Viaskin Peanut in 221 peanut allergic subjects with a well-documented medical history of systemic reactions after ingestion of peanut. Subjects 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 subjects 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 subjects, ages 6-11) for the first stratum and adolescents (73 subjects, ages 12-17) plus adults (35 subjects, ages 18-55) for the other stratum. Each patient underwent two double-blind, placebo-controlled food challenges, or 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 peanut tolerance level. 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 (age 18-55) and adolescents (age 12-17) or on the back of children (age 6-11).

Table of Contents

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 30mg for children and 100mg 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 double-blind, placebo controlled food challenge, 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, Cumulative Reactive Dose, or CRD, was also used to establish the total quantity of peanut protein that began triggering patient reactions at month 12 versus placebo. Serological markers were also measured as additional secondary endpoints at baseline, 3, 6 and 12 months in order to characterize the immunological changes in subjects. In terms of peanut consumption and immunological changes, a consistent dose effect was observed.

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 is also a member of our Scientific Advisory Board as well as principal investigator of the National Institutes of Health-sponsored Consortium of Food Allergy Research clinical trial with Viaskin Peanut (CoFAR6).

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 (AP-HP). He 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

In September 2014, we announced topline results for the VIPES trial, which was followed by a full study report 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 webcasted company-event following the AAAAI meeting.

[Table of Contents](#)

The primary efficacy endpoint was met with Viaskin 250 µg, with 50.0% responders vs 25.0% with placebo, $p=0.0108$ [Figure 1]. Moreover, children in the Viaskin 250 µg arm (6-11 years) exhibited 53.6% responders vs 19.4% for placebo, $p=0.0076$ [Figure 2]. 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 3]. Children's immunological responses were deemed to be robust. In the Viaskin 250µg 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 4].

Additional post-hoc analyses on the children stratum demonstrated that on a peanut consumption basis, a significant amount of patients were strong responders to treatment. In a post-hoc analysis, VIPES shows that 32.1%, 26.9% and 17.9% of children subjects in the Viaskin 250 µg, 100 µg and 50 µg arms, respectively, ingested both 10 times more peanut protein compared to baseline and at least 1,000 mg of peanut protein at month 12, compared to 0% in the placebo arm. We believe that this analysis confirms data presented by Dr. Sampson, which demonstrated both strong treatment and clear dose effect across the trial [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]. After our End of Phase II Meeting with the FDA, we will refine our development strategy for both peanut allergic adolescents and adults.

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 serious adverse events, or SAEs, but none related to study drug. Out the 20 serious adverse events, or SAEs, in VIPES, 16 were anaphylaxes during the DBPCFC; two were moderate anaphylaxes after accidental consumption of peanut containing foods outside of clinical trial site; there was also one respiratory distress case; and one psychiatric case. The trial drop-out rate was 6.4%, or 14 patients, which was below the 15% rate initially anticipated. Two out 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.

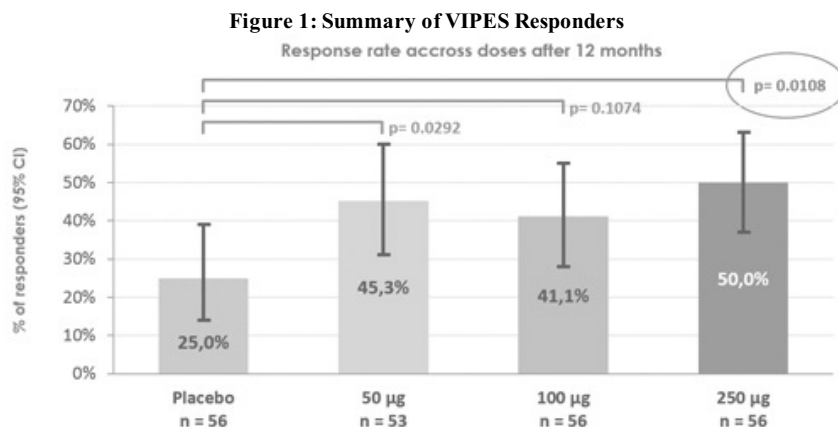


Figure 2: Summary of VIPES Responders: Children

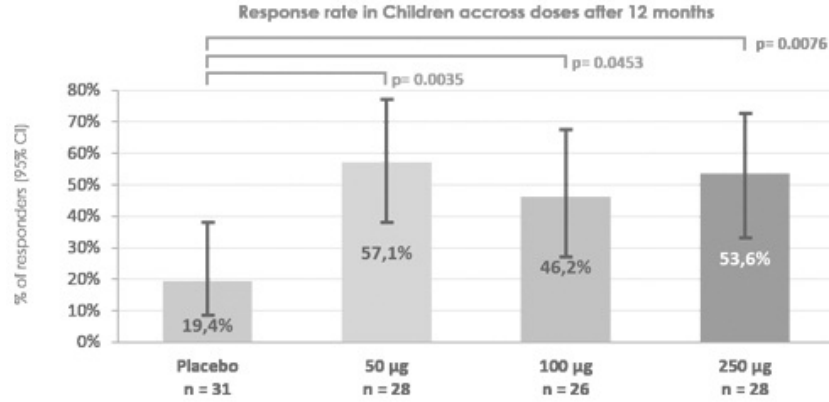


Figure 3: Summary of CRD Changes from Baseline in Children

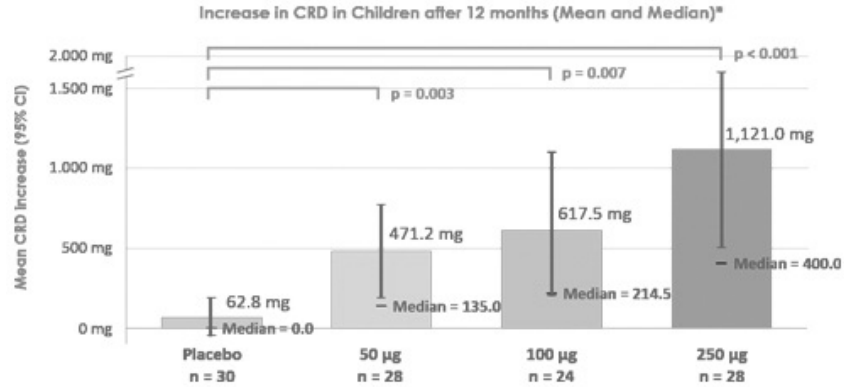


Figure 4: Summary of Immunological Responses in Children

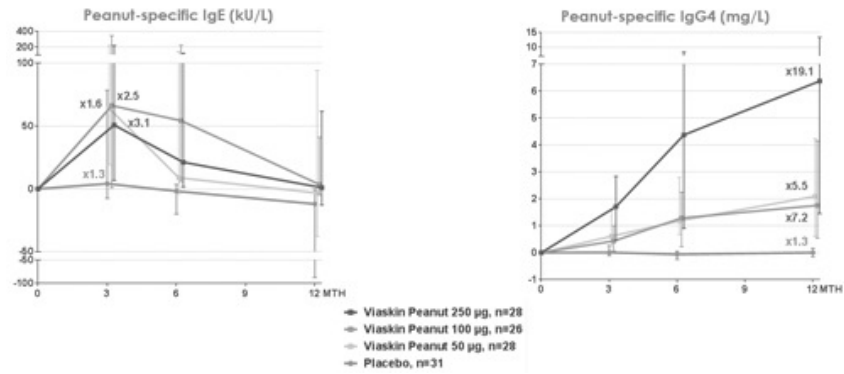


Figure 5: Summary of Children Ingesting 10 Times More Peanut Protein and at Least 1,000 mg of Peanut Protein at Month 12

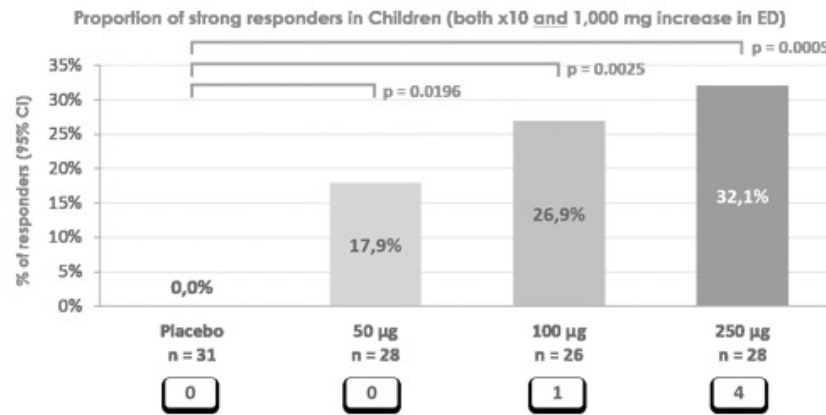
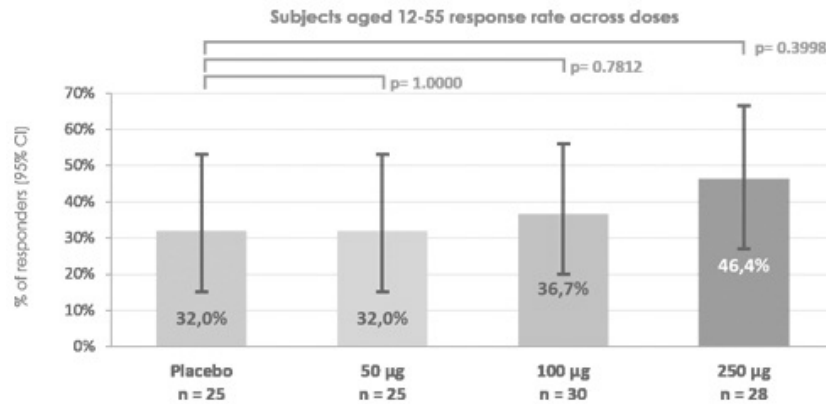


Figure 6: Summary of VIPES Responders: Adolescents and Adults



[Table of Contents](#)

VIPES OLFUS (Open-Label Follow-Up Study)

In September 2013, we initiated an open-label follow-up Phase IIb clinical trial called VIPES OLFUS to assess the long-term efficacy and safety of Viaskin Peanut in subjects with peanut allergy. VIPES OLFUS is an extension trial for subjects having completed 12 months of the VIPES double-blind, placebo-controlled clinical trial, during which all subjects will be treated with a 250 µg dose of Viaskin Peanut. VIPES OLFUS includes 170 subjects at 21 sites in North America and Europe, representing 82% of the patients who completed 12 months of therapy in the VIPES trial.

The objective of this trial is to assess the efficacy, safety and sustained tolerance of Viaskin Peanut after up to 36 months of epicutaneous immunotherapy in peanut allergic subjects.

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. In the trial, which was conducted at five leading centers in the United States, 100 subjects (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. Subjects with a history of severe anaphylactic reactions could be enrolled only after assessment of the safety of Viaskin Peanut in subjects 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 subjects that experience systemic reactions such as urticaria, asthma and acute dyspnea, change in blood pressure, and digestive symptoms (vomiting, diarrhea) associated with Viaskin Peanut treatment versus placebo, the proportion of subjects 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 (> 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 National Institute of Allergy and Infectious Diseases, or NIAID, of the United States National Institutes of Health has substantially increased its support for food allergy research since 2003, including the establishment of the Consortium for Food Allergy Research, or 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 CoFAR 6, 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 Professor Hugh Sampson in New York. The trial is being conducted in five hospitals in the United States and includes 75 patients, both adults and children. The recruitment of CoFAR6 ended in July 2014. Subjects will be randomized to two doses of Viaskin Peanut (100 µg and 250 µg) or matched placebo and will undergo a peanut protein oral food challenge at week 52. Expected to last four years, this trial will enable analysis of the effects of peanut desensitization with Viaskin Peanut over an initial period of 12 months.

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 5 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 6, 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 cumulative reactive dose, or CRD, greater than 1,000 mg of peanut protein (about 4 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 subjects), 6-, 12- and 18-month data showed 7.4%, 20% and 40% of subjects, 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 6, 12 and 18 months. In an analysis of 35 children (age 5 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, 6-, 12- and 18- month data showed 12.5%, 33.3% and 66.7% of subjects, 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

Cow's milk protein allergy, or CMPA, is 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 including 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, milk is the primary cause in two-thirds of the children with EoE. EoE is a debilitating disease involving esophageal dysfunction, due to massive and abnormal infiltration of eosinophil granulocytes in the esophagus and the upper digestive tract, with inflammation of the esophagus.

[Table of Contents](#)

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.

Development Program for Viaskin Milk

MILES (MILk Efficacy and Safety)

In November 2014, we initiated our MILES trial, a multi-center, double-blind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin Milk in pediatric patient populations (age 2 to 17) suffering from CMPA with elevated IgE levels related to cow's milk protein. We have an open IND for this trial. This trial is being conducted in select U.S. and Canadian clinical centers, including sites belonging to the CoFAR. Up to 150 subjects (18 subjects in Part A and 132 subjects in Part B) will be randomized for treatment at approximately 10 to 14 sites. Eligible subjects with confirmed IgE-mediated CMPA will perform a first food challenge at screening with escalating doses of cow's milk proteins. Subjects who show the appearance of objective signs or symptoms to an eliciting dose of cow's milk proteins ≤ 300 mg (approximately 9.4 mL of cow's milk) will be randomized in the trial.

Part A of MILES, which is equivalent to Phase I, will evaluate the safety of repeated daily applications of three escalating dose-levels of Viaskin Milk (150 μ g, 300 μ g and 500 μ g cow's milk protein) versus placebo during three weeks. Part B, which is equivalent to Phase II, is designed to evaluate the safety and efficacy of up to two selected doses of Viaskin Milk (as determined from Part A), after a review of the safety data. After month 12, all subjects from Parts A and B will continue treatment for another 12 months in an open-label manner with Viaskin Milk, at the highest dose determined to be safe based on safety data from Part A. The primary efficacy endpoint will be the percentage of subjects who are treatment responders after 12 months, defined as subjects who meet at least one of the following criteria: a ≥ 10 -fold increase in the cumulative reactive dose, or CRD, of cow's milk proteins at the month 12 food challenge as compared to baseline value and reaching at least 144 mg of cow's milk proteins (approximately 4.5 mL of milk); or a CRD of cow's milk proteins ≥ 1444 mg (approximately 45 mL of milk) at the month 12 food challenge. Secondary efficacy endpoints include, among other things, the percentage of subjects who are treatment responders at month 24, the mean and median CRD of cow's milk proteins at months 12 and 24 and change from baseline, the change in the severity of symptoms elicited during the food challenge from baseline to months 12 and 24, and the change from baseline in quality of life assessments at months 12 and 24.

Pilot Clinical Trial

Professor Christophe Dupont and the AP-HP conducted a double-blind, placebo-controlled pilot clinical trial of EPIT in 2005 in children (age 3 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 the *Journal of Allergy and Clinical Immunology* 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.

In addition, with assistance from us, The Children's Hospital of Philadelphia, or CHOP, intends to file an IND for a trial that we call SMILEE in the first half of 2015, a double-blind, placebo-controlled, randomized trial to study efficacy and safety of the Viaskin milk for treating milk-induced eosinophilic esophagitis in children, we expect the SMILEE trial will be conducted as follows, subject to the applicable institutional review board, or IRB, and FDA approval. Twenty subjects aged from 4 to 17 years will be randomized into either Viaskin Milk or placebo arms. Treatment will start at randomization, during which subjects will maintain a milk-free diet. After nine months of treatment, subjects will be re-exposed to milk for up to two months, at which point biopsies will be performed to evaluate primary endpoints.

[Table of Contents](#)

Although we are providing assistance in the form of funding and trial supplies, this trial will be conducted by CHOP and supervised by its staff member Jonathan Spergel, MD, PhD.

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 the second most common food allergy 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 recently begun pre-clinical work for this product candidate with the goal of initiating a clinical program if these studies are successful.

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 food allergy expertise, and will often seek to collaborate with companies or agencies that are experts in a particular field. 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. These programs and collaboration agreements are in the early proof-of-concept phase, and we do not expect to provide regular updates unless and until we elect to move one of them forward in a meaningful way. These preclinical assets include the following:

- Independently exploring Viaskin for the treatment of pediatric house dust mites allergy, which is one of the first causes of allergic asthma. We are currently conducting pre-clinical proof of concept and IND enabling studies for this product.
- With the University of Geneva and Bionet Asia, we are developing a booster vaccine against pertussis, for which a first clinical trial is planned to start in the next 12 months.

[Table of Contents](#)

- 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.
- With the French Institute for Agricultural Research, or INRA, we are developing a new vaccine strategy for respiratory syncytial virus, or RSV, in infants. This project seeks to offer a pre-clinical proof of concept for an innovative, safe and effective pediatric vaccine against RSV. This project is funded by the French National Research Agency, or ANR.
- With the Institut National de la Santé Et de la Recherche Médicale, or INSERM, we are developing a novel therapeutic strategy for hemophilia A with inhibitors.
- With Stallergènes S.A., we have signed a research and development agreement for developing a new treatment for birch pollen.

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, the Centre d'Immunologie de Marseille-Luminy, or CIML, in France 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.

Our First Marketing Experience: Diallertest Milk—A Ready-to-Use Patch Test For Detecting CMPA in Young Children

In 2004, we introduced to the French market Diallertest Milk, the first ready-to-use patch test for detecting CMPA in young children. Diallertest Milk is sold exclusively in France through a distribution partner. To date, sales of Diallertest Milk have been moderate, totaling approximately 25,000 kits per year on average over the past three years. We do not currently expect these product revenues to have a material impact on our business and financial condition in future periods.

In June 2009, we received a letter from the Agence Française de Sécurité Sanitaire des Produits de Santé (French Agency for the Safety of Health Products), informing us that, in its view, Diallertest Milk, although previously marketed as a medical device in France, met the criteria for a drug product and accordingly would be required to complete a Phase III marketing authorization study in accordance with the regulations in France applicable to the marketing of drug products. However, in light of the safety profile and perceived clinical utility of this product, the agency did not require that we discontinue the marketing and sale of Diallertest Milk and instead indicated that they would review with us our progress towards completing a Phase III trial at a later date. As of the date of this Annual Report on Form 20-F we have not yet initiated this Phase III clinical trial, as we continue to evaluate the commercial rationale for doing so. We are also evaluating potential marketing and/or distribution relationships to market this product in Europe.

There can be no assurance that the French regulatory authorities will continue to permit us to market and sell Diallertest Milk prior to the completion of a Phase III clinical trial for this product. We may also elect to discontinue the marketing and sale of this product on our own. See "Risk Factors—We are dependent on a single exclusive distributor for the marketing of our Diallertest Milk diagnostic product. We may discontinue our Diallertest Milk program."

Manufacturing and Supply

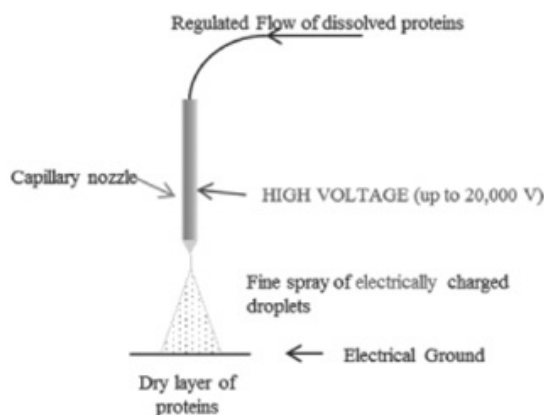
Our Proprietary Viaskin Technology

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. We believe this patented technology is highly scalable and complies with cGMP requirements.

The principles of the Viaskin electrospray technology are the following:



When a liquid flows at a constant speed 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 cone 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;
- 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.

[Table of Contents](#)

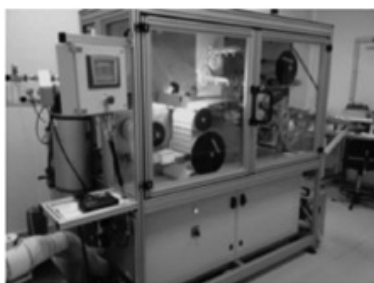
Viaskin is a Highly Scalable Manufacturing Technology

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

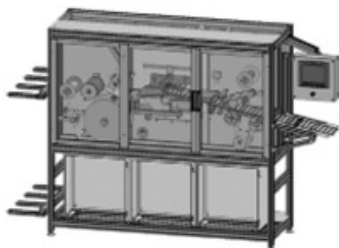
For our pre-clinical testing, we used two different prototypes. We then developed a third-generation machine in 2009 to manufacture patches for our clinical trials. For the Phase I and II of Viaskin Peanut and Viaskin Milk clinical trials, our electrospray machine, called GEN3.1, was able to produce 15,000 patches per batch, which was sufficient for our clinical needs. Overall, on a yearly basis, GEN3.1's throughput is approximately 750,000 patches.

We have assembled a new version of this tool, called GEN3.2 in 2014. This new generation manufacturing tool allows us to produce larger batch sizes of around 60,000 patches, which are compatible with our later-stage clinical development needs. Overall, on a yearly basis, GEN3.2's throughput is expected to be approximately 2,250,000 patches.

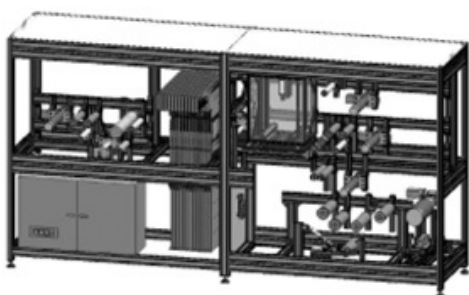
We believe that a commercial-scale version of our electrospray manufacturing tool called GEN4.0, will be completed in 2016. We anticipate this tool will allow us to produce commercial batch sizes, of around 500,000 patches, compatible with initial expected market demand. Overall, on a yearly basis, GEN4.0's throughput is expected to reach approximately 20 to 30 million patches.



GEN3.1 (2009)
18 nozzles
Used for Phase I and Phase II trials
Batch size: 15,000 patches
More than 200,000 produced since 2009



GEN3.2 (2014)
54 nozzles
Used for Phase III trials
Batch size: 60,000 patches
Improved electrospray process, forerunner of GEN4



GEN4 (expected 2016)
Assembly ongoing
Up to 300 nozzles Commercial products
Used for commercialization
Batch size: 500,000 patches

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 are in the process of selecting third-party manufacturers to manage our manufacturing process after the approval and during the commercialization of our Viaskin product candidates.

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, many 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 2028;
- 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 2027; 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 after the patent is granted. 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 January 7, 2009, we entered into an assignment, development and co-ownership agreement with Public Welfare-Hospitals of Paris (*L'Assistance Publique — Hôpitaux de Paris*), referred to herein as AP-HP, and Université Paris-Descartes, referred to herein as 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 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 varies depending on the particular patent used in the product and is in the low single digits. 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 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

[Table of Contents](#)

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 2028.

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, Allergen Research Corporation is currently evaluating in Phase II clinical trials a formulation of peanut flour for oral administration intended for oral desensitization. We are aware of other companies that are working on recombinant peanut proteins capable of initiating an attenuated immune response by using subcutaneous administration. We are also aware that Sanofi S.A. has entered into licensing agreements of discovery platforms in selected food allergies, notably with Immune Design Corp. and Selecta Biosciences Inc. and may pose a competitive risk to our products in the future.

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.

[Table of Contents](#)

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 discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial-related information, and it is possible that data and other information from trials involving drugs and biologics that never garner approval could require disclosure in the future. In addition, publication policies of major medical journals mandate certain registration and disclosures as a pre-condition for potential publication, even if not currently mandated as a matter of law. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

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

[Table of Contents](#)

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 product fee for human drugs and an annual establishment fee on facilities used to manufacture prescription 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.

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

[Table of Contents](#)

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 NDA 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.

[Table of Contents](#)

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 (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, risk minimization action plans 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

[Table of Contents](#)

FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs 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 criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. 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 BPICA, which was part of the ACA. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product

[Table of Contents](#)

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. However, complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being worked out by the FDA.

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 apply not earlier than May 28, 2016. 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, 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.

[Table of Contents](#)

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 State 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, 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 Huriot-Sérusclat Act of December 20, 1988. Article L. 1121-4 of the Public Health Code, as amended by the Act of August 9, 2004, now establishes a system of prior authorization issued by the ANSM with the favorable opinion of a competent Research and Ethics Committee for the place where the investigator exercises his activity. On the basis of Article L. 1123-7 of the same code, the 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; this procedure may not, however, be applied more than once. 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. 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.

[Table of Contents](#)

Personal data collected during clinical trials should be declared in simplified form to the Commission Nationale Informatique et Liberté, or CNIL. Patients then have a right to access and correct this data pursuant to Act No. 78-17 of January 6, 1978, as amended by law No. 2004-801 of August 6, 2004, concerning computing, files and freedoms.

The main French regulatory texts concerning the conduct of clinical trials are as follows:

- Law No. 2004-806 of August 9, 2004 related to the public health policy;
- Decision of November 24, 2006 establishing the rules for Good Clinical Practice;
- Decision of December 11, 2006 establishing the rules of good manufacturing practice;
- Law No. 2004-801 of August 6, 2004 and its decrees of application dealing with data protection;
- Law No. 2002-3003 of March 4, 2002 and its decrees of application relative to patient's rights and the quality of the healthcare system;
- Decision of January 5, 2006 concerning the approval of a methodology for the reference to the processing of personal data carried out within the context of biomedical research (reference methodology MR-001);
- Decree No. 2007-454 of March 25, 2007 concerning the conventions and the links uniting the members of certain healthcare professions to companies and amending the Public Health Code (regulatory provisions); and
- Law of March 13, 2000 relative to electronic signature and Decree 2001-272 of March 30, 2001, relative to electronic signature.

French Pharmaceutical Company Status

To date, we do not have the status of pharmaceutical establishment, 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

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 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

[Table of Contents](#)

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, is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the ACA on pharmaceutical companies as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred.

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. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering 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, started in April 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, 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.

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.

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 and state 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 laws 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,

[Table of Contents](#)

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;

- federal civil and criminal false claims laws and civil monetary penalty laws, 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit 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;
- the federal Physician Payments Sunshine Act, enacted as part of the ACA, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies 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 Health Information Technology and Clinical Health Act, or HITECH, 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 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 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, and state 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.

The ACA broadened the reach of the federal fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable federal criminal healthcare fraud statutes. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that 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 civil False Claims Act or the civil monetary penalties statute.

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, 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 exclusions from government funded healthcare programs.

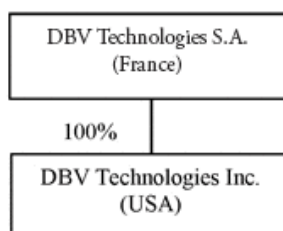
Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. 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.

[Table of Contents](#)

C. Organizational Structure.

The following diagram illustrates our corporate structure:



D. Property, Plants and Equipment.

We lease our office space, which consists of 1,479 square meters located in Bagneux, France. The lease for this facility expires on May 31, 2020. In order to accompany the growth of the company, we have concluded in January 2015 a lease agreement for 4,470 square meters of office and laboratory space located in Montrouge, France. We intend to move and leave the current premises later this year.

Item 4A. 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 Viaskin. We have generated significant data demonstrating that Viaskin's mechanism of action is novel and differentiated, as it targets specific antigen-presenting immune cells in the skin, called Langerhans cells, that capture the antigen and migrate to the lymph node in order to activate the immune system without passage of the antigen into the bloodstream. We are advancing this unique technology to treat patients, including infants and children, suffering from severe food allergies, for whom safety is paramount, since the introduction of the offending allergen into their bloodstream can cause severe or life-threatening allergic reactions, such as 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 offering of both ADSs on the Nasdaq and ordinary shares on Euronext Paris, of which we received net proceeds of €93.7 million.

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 administration 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;

[Table of Contents](#)

- 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 and operations as a U.S. public company.

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 will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to completing clinical development of our product candidates. Until such time that 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, and licensing arrangements. 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.

Our financial statements for 2012, 2013 and 2014 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 consist of revenues and other income.

Revenues

We derive substantially all of our revenues from sales of Diallyltest Milk, our diagnostic product for the detection of cow's milk protein allergy, or CMPA, in children sold exclusively in France through a distribution partner. To date, sales of Diallyltest Milk have been moderate, totaling approximately 25,000 kits per year on average over the past three years. Diallyltest Milk is currently available on the French market with a temporary exception status. Regulatory authorities are requesting a pivotal Phase III trial to complete the marketing authorization file for this product. We are examining the relevance of carrying out this clinical protocol, and are evaluating potential marketing and/or distribution relationships to market Diallyltest Milk in Europe in the field of pediatrics. We may also elect, or may be required at the request of regulatory authorities, to stop the marketing of Diallyltest Milk. We do not currently expect these product revenues to have a material impact on our business and financial condition in future periods.

Other Income

Government Assistance

Due to the innovative nature of our product candidate development programs, we have benefited from a certain 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 year 2013 during the year 2014. We have requested the reimbursement of the 2014 CIR under the Community tax rules for small and medium firms in compliance with the regulatory texts in effect for which we expect to be reimbursed in 2015. The CIR is presented under other income in our statement of income (loss). The CIR for the years 2008 and 2009 was subject to a tax audit in 2011. That audit, which ended on July 11, 2011, did not result in any significant adjustment.

Cost of Goods Sold

Because we are not classified as a pharmaceutical laboratory, we contract with a third party to manufacture our Diallertest Milk diagnostic patches according to current good manufacturing practices, or cGMPs. The cost of goods sold therefore includes the costs of manufacture we incur through this service provider.

Operating Expenses

Since inception, our operating expenses have consisted primarily of research and development activities and general and administration 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;

[Table of Contents](#)

- 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 allergies in adults, adolescents and children, for which a Phase IIb clinical trial called VIPES (Viaskin Peanut's Efficacy and Safety) was recently completed. In September 2014 we announced topline results for the VIPES trial and pending consultation with the FDA, we plan to initiate our Phase III trial for Viaskin Peanut in the first quarter of 2016. In September 2013, we initiated an open-label study called OLFUS (Open-Label Follow-Up Study) for VIPES, to evaluate the long-term efficacy and safety of Viaskin Peanut. VIPES OLFUS is a trial for subjects who completed 12 months in double blind in the VIPES trial. VIPES OLFUS is a multi-center clinical trial conducted in Europe and North America. It is planned to include 21 sites in four countries.
- **Viaskin Milk** for cow's milk protein allergy, or CMPA, in children for which we initiated a Phase I/II clinical trial in the United States and Canada in November 2014.
- **Scaling of the Viaskin technology** in order to be ready for the commercialization of Viaskin Peanut at a large scale.

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 studies, 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.

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.

[Table of Contents](#)

General and Administration

General and administration expense consists primarily of personnel costs and share-based compensation for personnel other than research and development staff. General and administration expense also consists of fees for professional services, mainly related to audit, IT and legal services, real-estate leasing costs, insurance costs and communication and travel costs, notably related to our being a public company in France.

We anticipate that our general and administration 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 commercialization of our product candidates. We also anticipate increased expenses associated with being a public company in the United States following the completion of our global public offering in October 2014, including costs related to audit, legal, regulatory and tax-related services associated with maintaining compliance with U.S. exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs.

Sales and Marketing

If and when we believe that a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Finance Income (Expense)

Our cash and cash equivalents have been deposited primarily in savings and deposit accounts with original maturities of three years or less, allowing the funds to be freely withdrawn at any time without notice or penalty. Savings and deposit accounts generate a modest amount of interest income. We expect to continue this investment philosophy.

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 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.

Conditional Advances

OSEO Innovation

Since inception we have received multiple interest-free conditional advances from OSEO Innovation, or OSEO, the French Agency for Innovation and part of the *Banque Publique d'Investissement*. OSEO's mission is to provide assistance and financial support to emerging French enterprises by providing such enterprises with growth capital to facilitate the development and commercialization of innovative technologies. Each award of a conditional advance is made to help fund a specific development project. See also, Note 11 to our audited consolidated financial statements for the years ended December 31, 2012, 2013 and 2014.

In the case of the conditional advances from OSEO, our obligation to repay these amounts is based on the technical and commercial success of the funded project, as determined by OSEO in its sole and subjective discretion. Once a project has been selected for funding by OSEO, both a payment and a repayment schedule are defined by contract. As the project advances, we provide OSEO with

[Table of Contents](#)

one or more interim progress reports and a final report when the funded project ends. Based on these reports, OSEO makes a subjective determination, in its sole discretion, as to whether the project is a partial or total technical or commercial success, or a technical or commercial failure. In the event OSEO determines that the project is a failure, we are required by contract to repay a minimum amount. In the event OSEO determines that the project is a partial success, there is a specified repayment schedule, provided that the parties may renegotiate a different repayment schedule in good faith. In the event OSEO determines that the project is a complete success, we are obliged to repay 100% of the amount of the conditional advance.

In the case of each conditional advance, we assume that OSEO will determine the project to be a total technical or commercial success and thus the maximum amount repayable with respect to such project will become due. However, actual results related to the development of these programs may differ from these estimates in which case the financial liability reflected in our statement of financial statements for the conditional advances may be reduced. The current and non-current portions of the financial liability recognized in our statement of financial statements associated with these conditional advances are determined based on the applicable reimbursement schedules at the end of each reporting period. The portion of the conditional advances for terms longer than one year is classified as a non-current liability while the portion for terms of less than one year is classified as a current liability. In addition, in the case of each conditional advance, we treat the benefit resulting from the interest-free nature of the award as a subsidy and recognize this amount as other income over the applicable repayment period. We determine the amount of this deemed subsidy amount 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 addition to the conditional advances described above, since inception we have received one non-refundable subsidy from OSEO, in connection with our development of our house dust mite product candidate. We refer to this development program as the ImmunaVia project. We account for this non-refundable subsidy as other income ratably over the duration of the funded project.

French Export Credit Insurance Company

In September 2007, we entered into an agreement with the French Export Credit Insurance Company, or COFACE, to support the promotion of our Diallyltest Milk product internationally. COFACE offers and manages, on behalf and under the guarantee of the French State, public guarantees to support exportations and investments made by French companies abroad. Under the terms of this agreement, we must repay these advances at up to 7% of the revenues from the export of our Diallyltest Milk until April 30, 2017. To date our export revenues for Diallyltest Milk have been modest. Diallyltest Milk is currently available with a temporary exception status from French regulatory authorities. Regulatory authorities in France have requested a pivotal Phase III trial to complete the marketing authorization file for this product. We are examining the relevance of carrying out this clinical protocol, and are evaluating potential marketing and/or distribution relationships to market Diallyltest Milk in Europe in the field of pediatrics. We may also elect, or may be required at the request of regulatory authorities, to stop the marketing of Diallyltest Milk. We do not currently expect these product revenues to have a material impact on our business and financial condition in future periods.

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 95% of the average of the closing sales price per ordinary share for the 20 trading days preceding the grant.

[Table of Contents](#)

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 a sufficient historical dataset.

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		
	2012	2013	2014
Volatility	40%	40%	40%
Risk free interest rate	1.21%-2.61%	1.16%-1.72%	0.71%-0.89%
Expected life (in years)	5.5-7.0	7.0	5.0-6.0
Dividend yield	—	—	—

For 2012, 2013 and 2014, we recorded employee share-based compensation expense of €3.2 million, €5.0 million and €4.6 million, respectively.

A. Operating Results

Comparisons for the Years Ended December 31, 2012 and 2013

Operating Income

We generated operating income of €2.8 million in 2012 and €3.8 million in 2013, an increase of 37.9%. These incomes were mainly generated by our CIR, and more marginally, by Diallertest Milk sales, and by subsidies received for research projects conducted by us.

	December 31	
	2012	2013
	€	€
Revenues	174,360	181,800
Other income	2,602,228	3,644,513
o/w CIR	2,522,399	3,312,462
o/w subsidies	79,829	332,051
Total income	2,776,588	3,826,313

As no research and development expenditure is capitalized before obtaining a marketing authorization, the CIR related to such research programs is entirely recorded as operating income. The grants we received during the period were deducted from the calculation of the CIR base.

[Table of Contents](#)

For the year ended December 31, 2013, we recorded other income related to CIR of €3.3 million, which we requested for reimbursement in 2014. In 2013, we received the reimbursement of €2.5 million for the 2012 CIR under the Community small and medium business scheme.

The increase of €790,063, or 31.3%, in the CIR recorded in 2013 reflects the acceleration of our various development programs in 2013.

The revenues generated by Diallertest Milk, which is only marketed in France through a distributor, increased by 4.3% during the last financial year, from €174,360 in 2012 to €181,800 in 2013. We do not currently expect these product revenues to have a material impact on our business and financial condition in future periods.

The increase of €252,222 in subsidies recorded in 2013 was due to the grant of the fourth OSEO advance.

Cost of Goods Sold

Because we are not classified as a pharmaceutical laboratory, we contract with a third party to manufacture our Diallertest Milk diagnostic patches according to the cGMP. The cost of goods sold therefore includes the costs of manufacture through this service provider. The cost of goods represented 47.6% and 56.3% of our sales revenues in 2012 and 2013, respectively.

	December 31	
	2012	2013
	€	€
Cost of goods sold	82,958	102,366

Research and Development Expenditures

From 2012 to 2013, the total amount spent by us for research and development activity increased from €11.5 million to €17.4 million, or an increase of 51.0%.

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

- **Viaskin Peanut** for the treatment of peanut allergies in adults and children, for which the VIPES trial was recently completed. In September 2014 we announced topline results for the VIPES trial and pending consultation with the FDA, we plan to initiate our Phase III trial for Viaskin Peanut in the first quarter of 2016. In September 2013, we initiated VIPES OLFUS trial to evaluate the long-term efficacy and safety of Viaskin Peanut. VIPES OLFUS is an extension trial for subjects who completed 12 months in double blind in the VIPES trial. VIPES OLFUS is a multi-center trial conducted in Europe and North America. It is planned to include 21 sites in four countries.
- **Viaskin Milk** for CMPA in children for which a Phase I/II clinical trial is starting in the United States and Canada.
- **Scaling of the Viaskin technology** in order to be ready for the commercialization of Viaskin Peanut at a large scale.

Table of Contents

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 studies, 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 as described in the table below:

	December 31	
	2012	2013
	€	€
Viaskin Peanut ⁽¹⁾	—	6,503,562
Viaskin Milk	—	957,714
Total direct research and development expenses⁽¹⁾	—	7,461,276
Personnel expenses	4,800,518	7,194,722
Other Viaskin- & EPIT-related expenses ⁽¹⁾	5,922,763	1,690,826
Facility expenses	259,224	263,438
Conferences, travel expenses	324,123	465,871
Depreciation, amortization and provisions	192,740	290,406
Personnel and other expenses⁽¹⁾	11,499,368	9,905,262
Total R&D expenses	11,499,368	17,366,538

- (1) In 2012, all resources in research and development were indirectly dedicated to Viaskin Peanut, since it was our only active program at the time. However, as of 2013, our resources were allocated to our two lead programs as well as more broadly to the Viaskin platform and the EPIT methodology, including the scaling of our technology to prepare for the commercialization of Viaskin Peanut.

The increased expenditures from year to year resulted from the costs associated with the VIPES Phase IIb trial of the Viaskin Peanut that began during the summer of 2012, as well as a substantial strengthening of research and development teams due to the increasing number of active programs.

In particular, we have incurred:

- an increase of total payroll dedicated to research and development of 49.9%, resulting in both an increase in staff from 26 employees at the end of 2012 to 33 employees at the end of 2013, and in the expense related to granting performance shares and stock options to employees in 2013;
- an increase of 57.0% of subcontracting and collaborations that includes the costs of service providers within the conduct of the VIPES Phase IIb trial in 2013;
- an increase in travel expenses of 43.7%, in line with the increase in our research and development staff; and
- an increase in depreciation, amortization and provisions of 50.7%, reflecting our increased investment in capital equipment.

General and Administration Expenses

During the period presented, our general and administration expenses increased from €4.6 million to €6.3 million, or an increase of 37.2%.

Our general and administration expenses break down as follows:

	December 31	
	2012	2013
	€	€
Personnel expenses	3,107,246	4,698,848
Fees	512,709	586,638
Real estate leasing	157,467	111,232
Insurance	56,054	105,018
Communication and travel expenses	480,999	450,701
Telecommunication expenses	86,831	65,350
Administrative costs and rental of personal property	65,867	97,131
Other	131,526	194,832
Total G&A expenses	4,598,699	6,309,750

[Table of Contents](#)

General and administration expenses for the year ended December 31, 2012 were €4.6 million, compared to €6.3 million for the year ended December 31, 2013. The increase of €1.7 million in general and administration expenses was primarily due to increased personnel related costs of €1.6 million.

Financial Profit (Loss)

Our net financial profit increased to €645,925 in 2013 from €492,337 in 2012, an increase of 31.2%. The change in our financial profit in 2013 is mainly explained by the cash investment income we received, notably as part of capital increases completed in March 2012 and November 2013, the financial revenues having increased from €517,540 in 2012 to €670,234 in 2013.

Comparisons for the Years Ended December 31, 2013 and 2014

Operating Income

We generated operating income of €3.8 million in 2013 and €4.8 million in 2014, an increase of 24.4%. These incomes were mainly generated by our CIR, and more marginally, by Diallertest Milk sales, and by subsidies received for research projects conducted by us.

	December 31	
	2013	2014
	€	€
Revenues	181,800	210,759
Other income	3,644,513	4,550,763
o/w CIR	3,312,462	4,339,620
o/w subsidies	332,051	211,143
Total income	3,826,313	4,761,522

As no research and development expenditure is capitalized before obtaining a marketing authorization, the CIR related to such research programs is entirely recorded as operating income. The grants we received during the period were deducted from the calculation of the CIR base.

For the year ended December 31, 2014, we recorded other income related to CIR of €4.3 million, which we requested for reimbursement in 2015. In 2014, we received the reimbursement of €3.3 million for the 2013 CIR under the Community small and medium business scheme.

The increase of €1.0 million, or 31.0%, in the CIR recorded in 2014 reflects the acceleration of our various development programs in 2014.

The revenues generated by Diallertest Milk, which is only marketed in France through a distributor, increased by 15.9% during the last financial year, from €181,800 in 2013 to €210,759 in 2014. We do not currently expect these product revenues to have a material impact on our business and financial condition in future periods.

Cost of Goods Sold

Because we are not classified as a pharmaceutical laboratory, we contract with a third party to manufacture our Diallertest Milk diagnostic patches according to the cGMP. The cost of goods sold therefore includes the costs of manufacture through this service provider. The cost of goods represented 56.3% and 64.7% of our sales revenues in 2013 and 2014, respectively.

	December 31	
	2013	2014
	€	€
Cost of goods sold	102,366	136,296

[Table of Contents](#)

Research and Development Expenditures

From 2013 to 2014, the total amount spent by us for research and development activity increased from €17.4 million to €21.1 million, or an increase of 21.7%.

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

- **Viaskin Peanut** for the treatment of peanut allergies in adults and children, for which the VIPES trial was completed in 2014. In September 2014 we announced topline results for the VIPES trial and pending consultation with the FDA, we plan to initiate our Phase III trial for Viaskin Peanut in the first quarter of 2016. In September 2013, we initiated VIPES OLFUS trial to evaluate the long-term efficacy and safety of Viaskin Peanut. VIPES OLFUS is an extension trial for subjects who completed 12 months in double blind in the VIPES trial. VIPES OLFUS is a multi-center trial conducted in Europe and North America. It is planned to include 21 sites in four countries.
- **Viaskin Milk** for CMPA in children for which a Phase I/II clinical trial started in November 2014 in the United States and Canada.
- **Scaling of the Viaskin technology** in order to be ready for the commercialization of Viaskin Peanut at a large scale.

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 studies, 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 as described in the table below:

	December 31	
	2013	2014
	€	€
Viaskin Peanut	6,503,562	6,398,226
Viaskin Milk	957,714	2,555,090
Total direct research and development expenses	7,461,276	8,953,316
Personnel expenses	7,194,722	7,703,057
Other Viaskin- & EPIT-related expenses	1,690,826	3,100,554
Facility expenses	263,438	254,923
Conferences, travel expenses	465,871	665,420
Depreciation, amortization and provisions	290,406	466,172
Personnel and other expenses	9,905,262	12,160,126
Total R&D expenses	17,366,538	21,143,442

The increased expenditures from year to year resulted from the costs associated with both the VIPES Phase IIb and OLFUS-VIPES follow up trials of the Viaskin Peanut running alongside in 2014, the MILES Phase I/II trial of the Viaskin Milk initiated in November 2014, as well as a substantial strengthening of research and development teams due to the increasing number of active programs.

In particular, we have incurred:

- an increase of total payroll dedicated to research and development of 7.1%, resulting in both an increase in staff from 33 employees at the end of 2013 to 42 employees at the end of 2014, partly offset by a decrease in the expense related to granting performance shares and stock options to employees in 2014;

[Table of Contents](#)

- an increase of 30.3% of subcontracting and collaborations that includes the costs of service providers within the conduct of the VIPES Phase IIb, OLFUS-VIPES follow up and MILES Phase I/II trials in 2014;
- an increase in travel expenses of 42.8%, in line with the increase in our research and development staff; and
- an increase in depreciation, amortization and provisions of 60.5%, reflecting our increased investment in capital equipment.

General and Administration Expenses

During the period presented, our general and administration expenses increased from €6.3 million to €8.1 million, or an increase of 28.7%.

Our general and administration expenses break down as follows:

	December 31	
	2013	2014
	€	€
Personnel expenses	4,698,848	5,109,057
Fees	586,638	1,165,989
Real estate leasing	111,232	203,899
Insurance	105,018	230,495
Communication and travel expenses	450,701	645,175
Telecommunication expenses	65,350	75,913
Administrative costs and rental of personal property	97,131	104,374
Other	194,832	582,762
Total G&A expenses	6,309,750	8,117,664

General and administration expenses for the year ended December 31, 2013 were €6.3 million, compared to €8.1 million for the year ended December 31, 2014. The increase of €1.8 million in general and administration expenses was primarily due to:

- an increase of total payroll dedicated to administration and management of 8.7%, resulting in both an increase in staff from 11 employees at the end of 2013 to 14 employees at the end of 2014, partly offset by a decrease in the expense related to granting performance shares and stock options to employees in 2014;
- An increase in fees of 98.8%, mainly due to higher audit, consulting and legal services expenses generated by our being listed on Nasdaq;
- an increase of 33.2% in communication and travel expenses, mainly due to our being listed on Nasdaq and improving our presence in the US; and
- An increase in insurance of 119.5%, due to contracting a Directors & Officers insurance policy in the context of being listed on the Nasdaq.

[Table of Contents](#)

Financial Profit (Loss)

Our net financial profit decreased to €624,000 in 2014 from €645,925 in 2013, a decrease of 3.4%. The change in our financial profit in 2014 is mainly explained by the cash investment income we received, notably as part of capital increases completed in November 2013 and in October 2014, the financial revenues having increased from €670,234 in 2013 to €727,239 in 2014. This was partly offset by a net foreign exchange loss of €22,887, compared to a net gain of €10,289 in 2013.

B. Liquidity and Capital Resources

We have financed our operations since 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 the Nasdaq and ordinary shares on Euronext Paris, of which we received net proceeds of €93.7 million.

The table below summarizes our sources and uses of cash for the years ended December 31, 2012, 2013 and 2014.

	December 31		
	2012	2013	2014
	€	€	€
Cash used in operating activities	(10,432,549)	(13,253,215)	(20,559,652)
Cash used in investing activities	(368,760)	(1,408,425)	(1,096,231)
Cash flows provided by financing activities	37,098,822	16,235,770	96,808,306
Net increase in cash and cash equivalents	26,297,514	1,574,130	75,152,424

Our net cash flows used from operational activities was at €20.6 million, €13.3 million and €10.4 million for 2014, 2013 and 2012, respectively.

During 2013, our net cash flows used from operational activities increased due to our growing efforts in advancing our research and development programs, mainly Viaskin Peanut that progressed through its Phase IIb clinical trial. This increase was partially offset by a positive change in working capital of €574,252 over the period.

During 2014, our net cash flows used from operational activities increased due to further growing efforts in advancing our research and development programs, mainly Viaskin Peanut that runned both its Phase IIb and follow up clinical trials, and Viaskin Milk that initiated its Phase I/II clinical trial.

Our net cash flows used from investing activities stood at €1.1 million, €1.4 million and €368,760 in 2014, 2013 and 2012, respectively.

This significant increase both in 2013 and 2014 reflects the acquisition of industrial and laboratory equipment required to conduct our development programs, as well as the refurbishment of our research and development premises.

Our net cash flows provided from financing activities declined to €16.2 million in 2013 from €37.1 million in 2012, mainly due to the fact that we only raised €15.2 million in 2013.

Our net cash flows provided from financing activities increased to €96.8 million in 2014 from €16.2 million in 2013, mainly as result of our €104.5 million global offering of both ADSs on the Nasdaq and ordinary shares on Euronext Paris, of which we received net proceeds of €93.7 million, partially offset by an additional €900,000 to our liquidity contract.

Consistent with customary practice in the French securities market, we entered into a liquidity agreement (*contrat de liquidité*) with Natixis, dated 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 DBV shares on Euronext Paris. As of December 31, 2014, we have contributed an aggregate of €1.2 million to the liquidity account. The amount is classified in other non-current financial assets in our statement of financial position. At December 31, 2014, 8,054 shares and €1,111,227 were in the liquidity account. The liquidity agreement has a term of one year and will renew automatically unless otherwise terminated by either party.

[Table of Contents](#)

Cash and Funding Sources

During 2012, 2013 and 2014, we obtained new financing on the public markets by issuance of securities.

	Equity capital	Bank Loans	Other debt	Total
2012	40,626,662	—	—	40,626,662
2013	15,128,873	—	1,159,500	16,288,373
2014	93,711,030	—	3,128,000	96,839,030
Total	149,466,565	—	4,287,500	153,754,065

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

As of December 31, 2014, 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.

- 2nd OSEO advance: On January 10, 2005, we obtained a conditional advance of €600,000 from OSEO for a project to design a high-speed prototype machine to produce patches and to develop second-generation patches in particular intended for the detection of various allergies. The entire sum had been received as of December 31, 2010. The repayment of this grant was made in accordance with the initial schedule, with the final repayment made on April 2, 2013.
- 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.
- 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 HDM 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, €918,000 is expected in October 2015 and €481,162 is expected in April 2018. Unless OSEO deems our company to be a commercial failure, we will reimburse €400,000 no later than June 30, 2021, €800,000 no later than June 30, 2022, €1.1 million no later than June 30, 2023 and €1.5 million no later than June 30, 2024. In addition, we received from OSEO a total of €1,919,056 in the form of a non-refundable subsidy.
- COFACE advance: On September 6, 2007, we signed a prospecting insurance contract with COFACE in order to promote our Diallyrtest Milk internationally. For this purpose, we received conditional advances of €147,534. We must repay these advances at up to 7% of the revenues from the export of our Diallyrtest Milk until April 30, 2017. Since Diallyrtest Milk has been reclassified from a medical device to a drug product by the relevant French authorities, we may only market it for export after we complete a Phase III marketing authorization study in accordance with the regulations in France applicable to the marketing of drug products.

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.

Table of Contents

The activity for the conditional advances recorded during 2012, 2013 and 2014 is summarized in the table below:

	2nd OSEO advance €	3rd OSEO advance €	4th OSEO advance €	Bpi France interest-free loan €	COFACE €	Total €
Balance debt at 01/01/2012	450,713	246,238	—	—	122,501	819,452
+ receipts	—	—	—	—	—	—
- repayments	(200,000)	—	—	—	—	(200,000)
+/- other transactions(1)	6,701	3,661	—	—	4,251	14,613
Balance debt at 12/31/2012	257,414	249,899	—	—	126,752	634,065
+ receipts	—	256,000	903,500	—	—	1,159,500
- repayments	(260,000)	—	—	—	—	(260,000)
+/- other transactions(1)	2,586	(1,579)	(111,047)	—	19,300	(90,740)
Balance debt at 12/31/2013	—	504,320	792,453	—	146,052	1,442,825
+ receipts	—	128,000	—	3,000,000	—	3,128,000
- repayments	—	(128,000)	—	—	—	(128,000)
+/- other transactions(1)	—	2,276	12,932	(416,361)	4,994	(396,159)
Balance debt at 12/31/2014	—	506,596	805,385	2,583,639	151,046	4,046,666

(1) The changes in “other transactions” are comprised of the effect of discontinuing conditional advances.

Operating Capital Requirements

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements until the end of 2016. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. In any event, we will require additional capital to pursue pre-clinical and clinical activities, obtain regulatory approval for, and to commercialize our product candidates.

Until we can generate a sufficient amount of revenue from our product candidates, 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. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing shareholders, increased fixed payment obligations and these securities may have rights senior to those of our ordinary shares. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, 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. Any of these events could significantly harm our business, financial condition and prospects.

Our present and future funding requirements will depend on many factors, including, among other things:

- the size, progress, timing and completion of our clinical trials for any current or future compounds, including Viaskin Peanut;
- the number of potential new compounds we identify and decide to develop;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for our compounds and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these compounds;

[Table of Contents](#)

- selling and marketing activities undertaken in connection with the anticipated commercialization of the Viaskin Peanut product candidate and any other current or future compounds and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future potential partnership agreements on the Viaskin platform.

For more information as to the risks associated with our future funding needs, see the section entitled “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 2012, 2013 and 2014 have been related primarily to the acquisition of laboratory equipment and, secondarily, to the acquisition of computer and office equipment.

	December 31		
	2012	2013	2014
	€	€	€
Long-term intangible assets	21,024	81,385	30,695
Property, plant, and equipment	340,411	1,089,902	941,301
Long-term financial assets	7,325	237,138	124,235
Total	368,760	1,408,425	1,096,231

In 2012, we extended and refurbished our research and industrial development laboratories, for which we accounted for investments in property, plant and equipment of €164,000, of which €105,000 were spent on the acquisition of laboratory equipment, and €72,000 on the acquisition of our computer and office equipment.

In 2013, we have purchased tools and equipment for the design, the development and manufacture of industrial prototypes and tools for €399,000 and continued to expand and refurbish our research and industrial development laboratories for €292,000, of which €192,000 were spent on the acquisition of laboratory equipment, and €157,000 on the acquisition of computers and office equipment. Also, €81,000 was spent on acquisition of software packages, notably in the context of updating the accounting and management software.

In 2014, we have purchased tools and equipment for the design, the development and manufacture of industrial prototypes and tools for €608,000, €277,000 were spent on the acquisition of laboratory equipment. Also, €848,000 were allocated to additional funding of our liquidity contract, and €124,000 as a guarantee deposit in the context of expending our facilities.

JOBS Act Exemptions

We qualify as an “emerging growth company” as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- to the extent that we no longer qualify as a foreign private issuer, (1) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (2) exemptions from the requirements of holding a non-binding advisory vote on executive compensation, including golden parachute compensation.

[Table of Contents](#)

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of (1) the last day of the fiscal year in which we have more than \$1.0 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities; (3) the issuance, in any three-year period, by our company of more than \$1.0 billion in non-convertible debt securities held by non-affiliates; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We may choose to take advantage of some but not all of these exemptions. For example, Section 107 of the JOBS Act provides that an emerging growth company can use the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Given that we currently report and expect to continue to report under IFRS as issued by the IASB, we have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required by the IASB. We have taken advantage of reduced reporting requirements in this Annual Report on Form 20-F. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold equity securities.

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, 2014. Future events could cause actual payments to differ from these estimates.

	Less than 1 year €	1 to 3 years €	3 to 5 years €	More than 5 years €	Total €
Long-term debt obligations	212,653	437,238	1,536,666	1,914,266	4,100,823
Capital (finance) lease obligations	—	—	—	—	—
Operating lease obligations	—	—	—	—	—
Purchase obligations	—	—	—	—	—
Other long-term liabilities	—	—	—	—	—
Total	212,653	437,238	1,536,666	1,914,266	4,100,823

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. In 2015, we signed a new lease arrangement in relation to our new premises in Montrouge, France and expect to relocate our current site in Bagneux later in 2015.

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 Employee.

A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors, including their ages, as of March 31, 2015. Unless otherwise stated, the address for our executive officers and directors is Green Square-Bâtiment D, 80/84 rue des Meuniers, 92220 Bagneux, France.

Name	Age	Position(s)
Executive Officers:		
Dr. Pierre-Henri Benhamou	59	Chief Executive Officer, Chairman of the board and Co-Founder
Bertrand Dupont	63	Chief Technical Officer and Co-Founder
David Schilansky	39	Chief Operating Officer
Charles Ruban	43	Chief Development Officer
Non-Employee Directors:		
Dr. Torbjörn Bjerke ⁽¹⁾⁽²⁾	52	Director
Daniel Soland ⁽¹⁾⁽⁴⁾	59	Director
George Homer III ⁽¹⁾⁽²⁾	70	Director
Peter Barton Hutt	80	Director
Chahra Louafi	43	Director
Dr. Rafaële Tordjman ⁽²⁾⁽³⁾	45	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) As representative of Sofinnova Partners, the legal entity that holds this board seat.

(4) Appointed on March 6, 2015, in replacement of Didier Hoch who had resigned.

Dr. Pierre-Henri Benhamou, co-founded DBV in 2002, and has served as our Chief Executive Officer from 2002 to the present (except from 2006 to 2010, when he was Chief Scientific Officer) and Chairman of our board of directors since our initial public offering on Euronext Paris in March 2012. With Dr. Christophe Dupont, he described for the first time and patented the epicutaneous method of immunotherapy and explored with our scientific team the wide range of applications of the method. Dr. Benhamou is a physician, specializing in pediatric gastroenterology. He has held numerous clinical and academic positions. He received the Altran Foundation Prize for Innovation in 2003 for his work on the development of diagnostic patch tests. Dr. Benhamou has published numerous papers and originated key scientific collaborations for us and has been instrumental in forming our Scientific Advisory Board. Dr. Benhamou holds an M.D. from Faculté de Médecine de Paris in 1984 and his specialization degree in Pediatrics in 1987. The board of directors believes that Dr. Benhamou’s leadership, deep knowledge of our company and scientific experience will allow him to drive us to the success of our objectives.

Bertrand Dupont, one of our founders, has served as our Chief Technical Officer since 2002. He is a member of our Executive Committee. From 1977 to 2002, Mr. Bertrand has served as a professor at the high school and at the university, teaching mechanics and robotics. In 1996, Mr. Dupont began to put his skills and expertise to use in biomedical research. Since 2000, he has been at the core of the development of the Viaskin patches and applications. As our Chief Industrial Officer, Mr. Dupont is a key figure in the development of the Viaskin technology and the application systems. He is responsible for every technical development around the Viaskin technology: design of the Viaskin patch, in-house industrial patch filling processes, design and building of the machines which are developed by DBV. He is also responsible for the production of the finished product in the facilities of the CMO DBV partners. Mr. Dupont received an engineering degree from the School of Arts et Métiers of Paris in 1974 and an Aggregation in mechanical engineering in 1987.

[Table of Contents](#)

David Schilansky has served as our Chief Operating Officer since January 2015. Mr. Schilansky was our Chief Financial Officer from December 2011 to January 2015. He supervises all of our financial work, human resources, general secretary, communication, investor relations as well as our partnership and business development activities. He is a member of our Executive Committee. From 2006 to 2011, Mr. Schilansky held various important positions at the Ipsen Group, or Ipsen, including Interim Chief Financial Officer, Deputy Chief Financial Officer, 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 degree from Université de Paris Dauphine and a Master degree from Imperial College in London.

Charles Ruban has served as our Chief Development Officer since June 2012 and oversees all of our development activities from manufacturing and quality control to clinical trials and regulatory affairs. He is a member of our Executive Committee. From 2003 to 2012, Mr. Ruban held various executive positions at Stallergènes S.A., including Senior Vice President of Product Development, member of the Executive Committee, Director of Research & Development Program and Director of Supply Chain. From 1994 to 2003, Mr. Ruban spent nine years at Eurogroup Consulting Holding as a management consultant. Mr. Ruban received an Engineering degree from the Ecole Centrale de Lyon, trained at Harvard-MIT Division of Health Sciences and Technology for his Master of Science in Biomedical Engineering and graduated with an Executive MBA from INSEAD.

Dr. Torbjörn Bjerke has served as a member of our board of directors since 2006. Dr. Bjerke is the Chief Executive Officer of Karolinska Development AB. Previously, 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.

George Horner III has served as a member of our board of directors since 2010. Mr. Horner has over 40 years of experience as a pharmaceutical executive. Since 2009, Mr. Horner has served as a biotech executive consultant for several private companies in the United States and Europe. Before that, from 2006 to 2008, Mr. Horner was the Chief Executive Officer of Prestwick Pharmaceuticals, Inc., or Prestwick, and under his leadership, Prestwick obtained FDA approval for Tetrabenazine (TBZ), the first drug ever licensed in the United States to treat Huntington's disease patients. From 1996 to 2005, Mr. Horner was the Chief Executive Officer of Vicuron Pharmaceuticals, Inc. (previously known as Versicor), an anti-infective company that he grew from a market value of \$12.8 million to a sale to Pfizer for \$1.9 billion. He previously held numerous executive, general management, business development and marketing and sales positions at Abbott Laboratories and Bristol-Myers Squibb Company across four continents. Mr. Horner holds a AB of English History from Belmont Abbey College. From 2010 until its sale to AstraZeneca plc in July 2013, Mr. Horner was the chairman of the board of directors of Omthera Pharmaceuticals, Inc. The board of directors believes that Mr. Horner's extensive executive and management experience in the pharmaceutical industry worldwide allows him to make valuable contributions to the board of directors.

Peter Barton Hutt has served as a member of our board of directors since 2009. He brings extensive knowledge and first-hand experience of U.S. food and drug legislation to our company. Mr. Hutt is currently a senior counsel at Covington & Burling LLP, a Washington DC law firm, specializing in food and drug law, where he has been practicing law since 1975. Mr. Hutt also teaches food and drug law at Harvard Law School. He has been a member of the U.S. Institute of Medicine since its establishment in 1971 and was former Chief Counsel for the FDA from 1971 to 1975. Mr. Hutt serves on the boards of directors of Momenta Pharmaceuticals, Inc., Xoma Corp., Concert Pharmaceuticals Inc. and BIND Therapeutics, Inc. From 2008 to 2011, he served on the board of directors of Celera Corp. and from 2002 to 2012, he served on the board of directors of Ista Pharmaceuticals, Inc., Mr. Hutt holds a B.A. from Yale University, a LL.B. from Harvard Law School and a LL.M. in Food and Drug Law from New York University School of Law. The board of directors believes that Mr. Hutt's extensive experience in the food and drug law and FDA matters allows him to make valuable contributions to the board of directors.

Chahra Louafi has served as a member of our board of directors since December 2010. Ms. Louafi is the Investment Director at Bpifrance Investissement, the fund manager for InnoBio FCPR, where she joined in 2001. Since October 2009, she has served the management team of InnoBio, a fund dedicated to biotech companies, managed by Bpifrance Investissement and invested by the pharmaceutical industry. Before that, she was at Mendel Partner in charge of initiating and implementing projects, as well as creating private business incubator specialized in biotechnology. Ms. Louafi serves on the boards of directors of Cysogene SAS and Pixium Vision SA. In addition, Ms. Louafi is the Chairman of the supervisory board of Inserm Transfert Initiative and a member of the

[Table of Contents](#)

supervisory board of Cap Décisif Management. Ms. Louafi graduated from Paris Dauphine University with a Masters of Technology and Innovation Management, from Paris X Nanterre University with a Masters of Corporate Finance, and from Institut National Agronomique de Paris—Grignon with a Masters of Microbiology and Enzymatic Engineering. The board of directors believes that Ms. Louafi's extensive investment experience in biotechnology industry allows her to make valuable contributions to the board of directors.

Rafaële Tordjman, MD, Ph.D., has served as a member of our board of directors since 2005. She joined the French venture capital firm Sofinnova Partners in 2001 and is a Managing Partner specializing in life sciences investments. Prior to this, she worked as a research scientist at the Institut National de la Recherche Médicale (INSERM) in Cochin Hospital, Paris. Before joining INSERM, she was a medical doctor specializing in clinical haematology and internal medicine. She obtained her PhD, with high honors, in haematopoiesis and angiogenesis from the University Paris VII followed by a post-doctoral fellowship in immunology. Rafaële obtained her medical degree and her specialization in Haematology and Internal Medicine as a five-year fellow in Paris University Hospitals. She also participated in the "Young Manager Program" at INSEAD (France, in 2002). She is a member of the board of directors of Ascendis Pharma GmbH, Flexion Therapeutics, Inc., Nucana Biomed, MedDay and ObsEva. She was also on the board of Corevalve, Endoart before it was successfully sold to Allergan Inc., of Preglem before the latter was successfully sold to Gedeon Richter and of HBI Ltd before being acquired by Meda. The board of directors believes that Dr. Tordjman's extensive clinical and research experience and pharmaceutical industry experience 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 Tarsa Therapeutics. 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. Earlier, he was President and CEO 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 BS in Pharmacy degree from the University of Iowa. The board of directors believes that Mr. Horner's extensive executive and management experience in the pharmaceutical industry worldwide, notably at various senior commercial operations positions, allows 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 paid and benefits in kind granted by us to our current executive officers and directors, including share-based compensation, for the year ended December 31, 2014, was €4.3 million. For the year ended December 31, 2014, €47,992 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

Our shareholders at the ordinary shareholders' general meeting of June 6, 2012 set the total annual attendance fees to be distributed among non-employee directors, except those who are affiliated with one of our significant shareholders, at €100,000. This authorization is automatically renewed each year, unless otherwise decided by our shareholders at an ordinary shareholders' general meeting. On September 25, 2012, upon recommendation of our compensation committee, our board of directors set attendance fee for these non-employee directors at €2,500 per meeting. The following table sets forth information regarding the compensation earned by our directors who are not executive officers or affiliated with one of our significant shareholders for service on our board of directors during the year ended December 31, 2014. Dr. Benhamou, our Chief Executive Officer, Chairman and Co-Founder, is a director but does not receive any additional compensation for his services as a director.

Name	Fees Earned (€)	Warrants(1) (€)	Total (€)
Torbjörn Bjerke	10,000	12,450	22,450
Didier Hoch (2)	10,000	12,450	22,450
George Horner III	10,000	12,450	22,450
Peter Barton Hutt	10,000	12,450	22,450

Table of Contents

- (1) Granted in 2014. This column reflects the full grant date fair value for warrants granted during 2014 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.
- (2) Mr. Hoch resigned from the board of directors in agreement with Bpifrance in March 2015.

Our other directors receive no compensation for their service as directors but are reimbursed for reasonable expenses incurred in connection with attending board and committee meetings.

CEO Compensation

The following table sets forth information regarding compensation earned by Dr. Benhamou, our Chief Executive Officer, Chairman and Co-Founder, during the year ended December 31, 2014.

Name and Principal Position	Salary (€)	Bonus (€)	Equity Awards (€)	Non-Equity Incentive Plan Compensation (€)	All Other Compensation (€)	Total (€)
Pierre-Henri Benhamou <i>Chief Executive Officer, Chairman and Co-Founder</i>	318,500	109,200(1)	1,140,600(2)(3)	—	—	1,573,760

- (1) The bonus awarded to Dr. Benhamou for 2014 amounted to €114,660 and was paid in January 2015.
- (2) This column reflects the full grant date fair value for equity awards granted during the year 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 executive officer 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.
- (3) The acquisition of the free shares is subject to the achievement of two performance criteria: (A) half of the allocated shares will be acquired at the later of the following dates: (i) expiration of a period of two years from the grant and (ii) inclusion of the 100th patient in the Phase III study of Viaskin Peanut no later than 12 months after enrollment of the first patient in the study; and (B) half of the allocated shares will be acquired at the later of the following dates: (i) expiration of a period of two years from the grant and (ii) approval of the protocol of the Viaskin Peanut Phase III by the FDA.

Executive Compensation Arrangements

For a discussion of our employment arrangements with our executive officers, see “Item 7.C—Related Party Transactions—Arrangements with Our Directors and Executive Officers.” Except the arrangements described in “Item 7.C—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.

[Table of Contents](#)

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, 2014, employee warrants, non-employee warrants, employee share options and free share were allowing for the purchase of an aggregate of 2,207,530 ordinary shares at a weighted average exercise price of €6.68 per share (not including the 641,360 ordinary shares issuable upon the vesting of outstanding free shares that may be issued for free with no exercise price being paid).

[Table of Contents](#)

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 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
<i>including those granted to Pierre-Henri Benhamou</i>	—	—	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, 2014 ⁽¹⁾	—	34,440	46,005	15,000
Total number of BCPCEs canceled or obsolete as of December 31, 2014	—	—	—	—
Total number of BCPCEs outstanding as of December 31, 2014	5,358	—	20,933	9,039
Total number of shares available for subscription as of December 31, 2014 ⁽¹⁾	80,370	—	313,995	135,585

- (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 BSPCE 4, BSPCE X and BSPCE 2010 granted on June 2011 are exercisable. Except for 2,509 BSPCE 2010 which shall become exercisable on November 22, 2015, all 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.

Table of Contents

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 six types of non-employee warrants (BSA) as follows as of December 31, 2014:

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	307,468
Total number of BSAs granted	1,717	10,716	306	1,825	10,039	8,000	1,338	89,835	30,000	73,000	10,000
<i>Including those granted to Pierre-Henri Benhamou</i>											
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	12/7/2015	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, 2014	—	40,005	—	—	37,650	—	15,060	—	5,000	2,500	—
Total number of BSAs canceled or obsolete as of December 31, 2014	572	—	—	—	—	—	—	—	—	—	—
Total number of BSAs remaining as of December 31, 2014	1,145	8,049	306	1,825	—	8,000	334	89,835	25,000	70,500	10,000
Total number of shares available for subscription as of December 31, 2014(1)	17,175	120,735	4,590	27,375	—	120,000	5,010	89,835	25,000	70,500	10,000

(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.

All BSA, BSA2 and BSA X are exercisable. All BSA 2010 are exercisable except for:

- 334 BSA 2010 which shall become exercisable on November 22, 2015; and
- 89,835 BSA 2010 which shall become exercisable on January 17, 2016.

All BSA 2012, 2013 and 2014 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.

[Table of Contents](#)

Share Options (OSA)

We have granted share options to our employees and our officers pursuant to our 2013 Share Option Plan, or 2013 Plan, and our 2014 Share Option Plan, or 2014 Plan. Our current plan, the 2014 Plan, was adopted by our board of directors on June 3, 2014.

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.

The maximum number of our ordinary shares that may be issued pursuant to share options granted under the 2013 Plan and 2014 Plan are 518,000 and 322,405, 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
Meeting date	12/9/2011	6/3/2014
Date of allocation by the Board of Directors	9/18/2013	6/3/2014
Total number of options authorized	1,968,528	922,405
Total number of options granted	518,000	75,000
<i>Including those granted to Pierre-Henri Benhamou</i>	129,000	—
Start date for the exercise of options ⁽¹⁾	9/19/2017	6/4/2016
Options expiry date	9/18/2023	6/3/2024
Options exercise price	€ 7.57	€ 19.01
Number of shares subscribed as of December 31, 2014	—	—
Total number of options canceled or obsolete as of December 31, 2014	47,000	—
Total number of options remaining as of December 31, 2014	471,000	75,000
Total number of shares available for subscription as of December 31, 2014	471,000	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) occurring prior to September 19, 2017, or June 4, 2016, as applicable, all of the options could be exercised in advance.

Our board of directors has set at 10% the number of acquired shares that must be kept by Dr. Pierre-Henri Benhamou in registered form until the cessation of his duties.

Administration. Our board of directors has the authority to administer the 2013 Plan and 2014 Plan. Subject to the terms of the 2013 Plan or 2014 Plan, 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 2013 Plan or 2014 Plan 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.

[Table of Contents](#)

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 2013 Plan and 2014 Plan, 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 and 2014 Free Share Plans, we have granted free shares to our employees and officers. Our current plan, the 2014 Free Share Plan, was adopted by our board of directors on June 3, 2014.

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 under the 2012, 2013 and 2014 Free Share Plans is 641,360. 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 grant as of December 31, 2014 are as follows:

Meeting date	INFORMATION REGARDING FREE SHARES				
	December 09, 2011	December 09, 2011	December 09, 2011	December 09, 2011	June 3, 2014
Date of the Board of Directors' meeting	April 02, 2012	July 25, 2012	November 28, 2012	July 25, 2013 September 12, 2013	June 3, 2014
Total number of free shares granted	669,796	134,081	35,360	501,500	186,000
Number of shares granted to Pierre-Henri Benhamou	304,461	—	—	58,500	60,000
Date of definitive acquisition of free shares (subject to the conditions of acquisition)(1)	April 2, 2014(2)(3)	July 25, 2014(2)(3)	November 28, 2014	July 25, 2015(2)(4)	June 3, 2016(2)(5)
End date of retention period	April 02, 2016(2)	July 25, 2016(2)	November 28, 2016	July 25, 2017(2)	June 3, 2018(2)
Number of shares acquired definitively as of December 31, 2014	667,936	134,081	35,360	—	—
Cumulative number of free shares canceled or lapsed as of December 31, 2014	1,860	—	—	81,500	—
Shares acquired free of charge remaining as of December 31, 2014 (in acquisition period)	—	—	—	420,000	186,000

- (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.

Table of Contents

- (2) The acquisition and retention period end date start on achievement of performance criteria for executive officers. See (3), (4) or (5) below.
- (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 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 VIPES Phase IIb clinical trial.
 - One-third of the shares allocated to executive officers 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 IIb clinical trial.
 - One-third of the shares allocated to executive officers 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 IIb clinical trial.
- (4) 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 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 clinical trial a maximum of 12 months after the inclusion of the first patient in the trial.
 - One-third of the shares allocated to executive officers 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 the protocol for the Phase III trial of Viaskin Peanut.
 - One-third of the shares allocated to executive officers 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 50% for five consecutive days of our share price compared with the closing price of our 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 (as defined in Article L. 233-3 of the French Commercial Code), the performance criteria will be considered as definitively achieved.
- (5) The acquisition of free shares is conditional for executive officers, including Dr. Benhamou, to the achievement of the three performance criteria below:
- 50% of the shares allocated to executive officers 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 clinical trial at the latest 12 months after the inclusion of the first patient in the trial.
 - 50% of the shares allocated to executive officers 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 the protocol of VIPES Phase III.
 - It is specified that in the event of a change of control (as defined in Article L. 233-3 of the French Commercial Code), the performance criteria will be considered as definitively achieved.

Dr. Pierre-Henri Benhamou shall keep 10% of his free shares under the registered form until the cessation of his duties.

Unless stated otherwise, the acquisition of the free shares allocated to Company employees are not subject to the achievement of performance criteria.

Administration. Our board of directors has the authority to administer the 2012, 2013 and 2014 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 and the holding period two years from the end of the acquisition period, it being specified that no holding period will be applicable to the beneficiaries for whom the acquisition period is at least 4 years).

[Table of Contents](#)

The board of directors has the authority to modify awards outstanding under our 2012, 2013 and 2014 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 2012, 2013 and 2014 Free Share Plans will be definitively acquired at the end of the acquisition period as set by our board of directors (of a minimum of two years) 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 (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.

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 definitively 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.

Amendment and Termination. Our board of directors has the authority to amend, alter, suspend, or terminate our 2012, 2013 and 2014 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 seven directors, less than a majority of whom are citizens or residents of the United States. As permitted by French law, one of our directors is a legal entity. The entity has designated an individual to represent it and to act on its behalf at meetings of our board or directors. This representative has the same responsibilities to us and to our shareholders as she would have if she had been elected to our board of directors in her individual capacity. While the currently designated representative has served in that capacity since the entity was elected to our board of directors, the entity director retains the right to appoint a different representative at any time and there can be no assurance that the individual currently serving as the representative will continue in that capacity.

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. 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.

<u>Name</u>	<u>Current Position</u>	<u>Year of Initial Appointment</u>	<u>Term Expiration Year</u>
Pierre-Henri Benhamou	Chairman	2005	2016
Torbjörn Bjerke	Director	2006	2016
Daniel Soland ⁽³⁾	Director	2014	2016
George Homer III	Director	2010	2016
Peter Barton Hutt	Director	2009	2016
Chahra Louafi ⁽¹⁾	Director	2010	2016
Rafaële Tordjman ⁽²⁾	Director	2005	2016

[Table of Contents](#)

- (1) From December 2010 to July 2014, Ms. Louafi served on our board of directors as representative of Bpifrance Investissement, the legal entity that held this board seat. Since July 2014, Ms. Louafi has served as a member of our board of director.
- (2) As representative of Sofinnova Partners, the legal entity that holds this board seat.
- (3) Appointed on March 6, 2015, in replacement of Didier Hoch who had resigned.

In addition, Ms. Maïlys Ferrère was appointed as a non-voting observer pursuant to a shareholders' agreement and her current term expires in 2016.

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, Torbjörn Bjerke, George Horner III, Daniel Soland and Peter Barton Hutt 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 will be 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 intend to rely on the certain exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, including that (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 annual 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."

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 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.

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. Our audit committee reviews our internal accounting procedures, consults with and reviews the services provided by our independent registered public accountants and assists our board of directors in its oversight of our corporate accounting and financial reporting. Dr. Bjerke, Mr. Homer and Mr. Soland currently serve on our audit committee. Dr. Bjerke is the chairperson of our audit committee. Our board has determined that each of Dr. Bjerke, Mr. Homer and Mr. Soland 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 Dr. Bjerke is an “audit committee financial expert” as defined by SEC rules and regulations and that each of Mr. Homer and Mr. Soland qualifies as financially sophisticated under the applicable exchange listing rules. We intend to comply with the applicable independence requirements with respect to our audit committee within the applicable time frame under the applicable transition rules of the SEC. The principal duties and responsibilities of our audit committee include (1) analyzing economic and financial information and (2) ensuring the accuracy and honesty of the our company’s financial statements, as well as the quality of the information provided.

Our board of directors has specifically assigned the following duties to the audit committee:

- with regard to our financial statements:
 - examine our draft budgets and draft annual financial statements, as well as our draft three-year plan before the board meets;
 - hear our statutory auditor to assist the board in its verification and control tasks;
 - evaluate and contribute to defining the applicable accounting, financial or ethical standards to be implemented by us, and prevent any potential violations in applying these standards;
 - examine draft comments, announcements and financial communications on the financial statements;
 - examine any contemplated issues of new securities or bonds by us; and
 - provide specific advice to our financial team at our company’s request.
- with regard to our external control system:
 - assess proposed nominations for our statutory auditors and their compensation, after receiving competitive bids; and
 - each year, with the statutory auditors, examine their action plans, findings and recommendations, as well as the follow-up given to them.
- with regard to our internal control and audit systems:
 - evaluate the group’s internal control systems with internal control managers; and
 - examine the audit programs and action plans with them, the findings of these interventions and actions, and make recommendations.

[Table of Contents](#)

- with regard to treasury:
 - examine general treasury policy (investments and borrowings, risk-hedging tools) and our cash situation.

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. Mr. Homer, Dr. Bjerke and Dr. Tordjman currently serve on the compensation committee. Mr. Horner is the chairperson of our compensation committee. The principal duties and responsibilities of our compensation committee include:

- propose the total compensation, retirement and social security systems and benefits in kind for corporate officers and members of our executive committee, based on an assessment of individual performance;
- propose the annual gross compensation of all managers whose compensation exceeds €100,000 per year, based notably on comparative market factors;
- as applicable, propose directors' attendance fees to be submitted to the general shareholders' meeting, as well as their distribution among board members;
- provide an opinion on our key guidelines with regard to compensation policy;
- give its opinion on the principles set by us with regard to profit sharing and shareholding; and
- give its opinion on funds allocated to board members elected by the employees, if applicable.

D. Employees.

As of December 31, 2014, we had 56 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,		
	2012	2013	2014
Function:			
Pre-clinical development and regulatory affairs	4	5	6
Clinical development	4	4	5
Research	13	18	24
Engineering and production	5	6	7
Management and administration	8	11	14
Total	34	44	56
Geography:			
France	34	44	55
United States	—	—	1
Total	34	44	56

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 March 24, 2015 for:

- each beneficial owner of more than five percent (5%) of our outstanding ordinary shares;
- 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 March 24, 2015. The percentage ownership information shown in the table is based upon 19,372,486 ordinary shares outstanding as of March 24, 2015.

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 March 24, 2015. 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., Green Square-Bâtiment D, 80/84 rue des Meuniers, 92220 Bagneux, France.

	Shares Beneficially Owned	
	Number	Percentage
5% Shareholders:		
Sofinnova Capital V FPCI ⁽¹⁾	2,269,254	11.71%
Entities Affiliated with Bpifrance ⁽²⁾	2,516,186	12.99
Entities Affiliated with Baker Bros. Advisors LP ⁽³⁾	1,885,780	9.73
Directors and Executive Officers:		
Pierre-Henri Benhamou ⁽⁴⁾	705,956	3.64
Torbjörn Bjerke ⁽⁵⁾	35,925	*
Daniel Soland ⁽⁶⁾	—	*
George Homer III ⁽⁷⁾	45,150	*
Peter Hutt ⁽⁸⁾	23,925	*
Chahra Louafi ⁽⁹⁾	2,516,186	12.99
Rafaële Tordjman ⁽¹⁰⁾	2,269,254	11.71
All directors and executive officers as a group (10 persons) ⁽¹¹⁾	6,245,705	32.24%

- (1) Consists of 2,269,254 shares. Dr. Tordjman is a partner of Sofinnova Partners SAS, the management company of Sofinnova Capital V FPCI and, in such capacity, Dr. Tordjman exercises voting and investment control over the ordinary shares held by Sofinnova Capital V FPCI. Dr. Tordjman disclaims beneficial ownership with respect to any such shares, except to the extent of her pecuniary interest therein, if any. The address of Sofinnova Capital V FPCI is 16-18 rue du Quatre Septembre, Paris 75002, France.

Table of Contents

- (2) Consists of 1,394,994 shares held by Bpifrance Participations S.A., or BpiP, and 1,121,192 shares held by Innobio FCPR, or Innobio. BpiP is the wholly-owned subsidiary of SA BPI-Groupe, or BPI. The Caisse des Dépôts et Consignations, or CDC, and EPIC BPI-Groupe, or EPIC, each hold 50% of the share capital of BPI and jointly control BPI. Innobio is managed by Bpifrance Investissement, or BpiI. BpiI is a wholly-owned, indirect subsidiary of BpiP. Nicolas Dufourcq is the Chief Executive Officer of BpiP and the President and Chairman of the Board of Directors of BpiI and may be deemed to have shared voting and investment power over the shares held by Innobio and BpiP. Paul-François Fournier is the director of the Innovation Business Unit of BpiP and BpiI and may be deemed to have shared voting and investment power over the shares held by BpiP and Innobio. Maïlys Ferrère is the director of the Large Venture Division of BpiP and may be deemed to have shared voting and investment power over the shares held by BpiP and Innobio. Laurent Arthaud is the director of Innobio and may be deemed to have shared voting and investment power over the shares held by BpiP and Innobio. None of BPI, CDC, EPIC, BpiI, Mr. Dufourcq, Mr. Fournier, Mr. Arthaud or Ms. Ferrère hold any shares directly. BPI may be deemed to be the beneficial owner of 2,516,186 shares, indirectly through its sole ownership of BpiP and its indirect ownership of Innobio. CDC and EPIC may be deemed to be the beneficial owners of 1,394,994 shares, indirectly through their joint ownership and control of BPI. BpiI, Mr. Dufourcq, Mr. Fournier and Mr. Arthaud may be deemed to be the beneficial owners of 1,121,192 shares through their control of Innobio. Mr. Dufourcq, Mr. Fournier, Mr. Arthaud and Ms. Ferrère disclaim beneficial ownership of such shares except to the extent of any pecuniary interest therein. The principal address for BpiP, BPI, EPIC, Innobio, BpiI, Mr. Dufourcq, Mr. Fournier, Mr. Arthaud and Ms. Ferrère is 27-31, avenue du Général Leclerc, 94710 Maisons-Alfort Cedex, France.
- (3) Consists of (a) 1,686,397 shares directly held by Baker Brothers Life Sciences, L.P., (b) 175,623 shares directly held by 667, L.P., and (c) 23,760 shares held by 14159, L.P. Baker Bros Advisor LP is the Investment Advisor of each of these funds and has sole voting and investment power with respect to the shares held by these funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Baker Bros. Advisors LP. The managing members of Baker Bros. Advisors (GP) LLC are Julian C. Baker and Felix J. Baker. Julian C. Baker and Felix J. Baker disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065. Based solely on a Schedule 13G filed by Baker Bros. Advisors LP on February 17, 2015.
- (4) Consists of (i) 314,706 shares held by Dr. Benhamou, (ii) 301,250 shares held by PHYS Participations, of which Dr. Benhamou owns 36.8% of the share capital and (iii) 90,000 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of March 24, 2015, subject to French law.
- (5) Consists of 35,925 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of March 24, 2015, subject to French law.
- (6) Daniel Soland was appointed to the board of directors on March 6, 2015, in replacement of Didier Hich who had resigned.
- (7) Consists of (i) 42,650 shares and (ii) 2,500 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of March 24, 2015, subject to French law.
- (8) Consists of 23,925 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of March 24, 2015, subject to French law.
- (9) Consist of shares described in note (2) above. Ms. Louafi is an Investment Director of Bpifrance Investissement. Ms. Louafi disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. Ms. Louafi's business address is 27-31, avenue du Général Leclerc, 94710 Maisons-Alfort Cedex, France.
- (10) Consist of shares described in note (1) above. Dr. Tordjman is a partner of Sofinnova Partners SAS, the management company of Sofinnova Capital V FPCI and, in such capacity, Dr. Tordjman exercises voting and investment control over the shares held by Sofinnova Capital V FPCI. Dr. Tordjman disclaims beneficial ownership with respect to any such shares, except to the extent of her pecuniary interest therein, if any. Dr. Tordjman's business address is 16-18 rue du Quatre Septembre, Paris 75002, France.

[Table of Contents](#)

- (11) Includes 405,670 shares issuable upon the exercise of options and warrants that are immediately exercisable or exercisable within 60 days of March 24, 2015, subject to French law.

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2012 are as a result of the transactions described in our prospectus dated October 22, 2014, filed with the SEC pursuant to Rule 424(b), under the heading “Related Party Transactions—Transactions with Our Principal Shareholders” and the dilution resulting from our recent public offering. None of our principal shareholders have voting rights different than our other shareholders.

As of January 15, 2015, assuming that all of our ordinary shares represented by ADSs are held by residents of the United States, we estimate that approximately 48.21% of our outstanding ordinary shares were held in the United States by 32 holders of record. At such date, there were outstanding 6,487,292 ADSs, each representing one half of one ordinary share, and in the aggregate representing 16.89% of our outstanding ordinary shares. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose 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, 2014, 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.

Shareholders’ Agreement

On March 9, 2012, Dr. Benhamou, PHYS Participations, Mr. Bertrand Dupont, DBCS Participations, Bpifrance Participations (formerly *Fonds Stratégique d’Investissement*) and our company entered into a shareholders’ agreement pursuant to which, (1) the parties entered into certain lock-up undertakings, (2) Bpifrance Participations is entitled to propose the appointment of one member of the board of directors (Dr. Didier Hoch was appointed, but resigned on February 16, 2015), which member shall serve on one of the board’s committees, (3) Bpifrance Participations is entitled to propose the appointment of one non-voting observer (currently Ms. Mailys Ferrère), and (4) Bpifrance Participations is entitled to certain information rights, subject to applicable laws and regulation. This shareholders’ agreement has a 10-year term and will automatically terminate if Bpifrance Participations ceases to hold at least 50% of the shares it held upon the first listing of the company on Euronext Paris.

Agreements with Our Directors and Executive Officers

Employment Arrangements

Pierre-Henri Benhamou

Dr. Benhamou, our Chief Executive Officer, does not have an employment agreement with the company. His compensation is determined by the board of directors upon recommendation of the compensation committee. On September 25, 2012, our board of directors resolved that in cases of (1) termination of Dr. Benhamou’s term as Chief Executive Officer of the company not due to a violation of the law or our By-laws or gross or severe negligence, or (2) non-renewal of Dr. Benhamou’s term against his will, and not due to a violation of the law or the our by-laws or gross or severe negligence, the company may pay him severance, the gross amount of which will be equal to the sum of the gross compensation he received from the company, of any kind whatsoever, over the 18 months preceding his termination if at least two of the following three criteria are met as of the date of his termination: (a) a management structure is in place permitting sale or collaboration involving Viaskin Peanut, with this criteria being considered as met if, on the date of his termination, all of the following positions are actually filled: technical director, director of development, financial director, head of strategic marketing and head of research; (b) stock market capitalization of the company equals to at least €80 million; (c) at least three Viaskin projects are in the process of development.

[Table of Contents](#)

We have entered into employment agreements with the following executive officers:

Bertrand Dupont

In January 2003, we entered into an employment agreement with Mr. Dupont, our Chief Technical Officer, which was amended as of January 1, 2006. Mr. Dupont is entitled to an annual base salary. Mr. Dupont is also eligible to receive equity grants as our board may determine and to participate in our bonus plan. In addition, Mr. Dupont's employment agreement provides for restrictions on certain competitive activities during the one-year period following the date of termination of his employment subject to the payment by us of a monthly compensation equal to 33% of the monthly gross salary paid to Mr. Dupont prior to his termination.

David Schilansky

In September 2011, we entered into an employment agreement with Mr. Schilansky, our Chief Operating Officer with an effective date as of September 30, 2011. Mr. Schilansky 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.

Charles Ruban

In May 2012, we entered into an employment agreement with Mr. Ruban, our Chief Development Officer with an effective date as of May 30, 2012. Mr. Ruban is entitled to an annual base salary. Mr. Ruban is also eligible to receive equity grants as our board may determine and to participate in our bonus plan.

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, 2014, we have granted equity awards to certain of our directors and executive officers.

On June 3, 2014, we issued 186,000 free shares, including 60,000 free shares granted to Dr. Benhamou and 90,000 free shares granted to other executive officers.

On June 3, 2014, we issued 10,000 non-employee warrants (BSA) as follows: (1) 2,500 BSA granted to Dr. Bjerke, (2) 2,500 BSA granted to Mr. Homer, (3) 2,500 BSA granted to Mr. Hutt and (4) 2,500 BSA granted to Dr. Hoch. Each BSA has been issued at purchase price per BSA of €1.88, and gives the right to subscribe for one ordinary share for a purchase price per share of €18.79.

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 entered 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.

[Table of Contents](#)**Legal Proceedings**

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. 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.

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.

B. Significant Changes.

On April 29, 2015, we reported that for the three months ended March 31, 2015, our total income was €1,453,706, up from €1,277,349 for the same period in 2014. This 13.8% increase partly resulted from an increase in Research Tax Credit, amounting to €1,275,595 over the period, compared to €1,227,140 in 2014, and also from the sales of Dialler test, which amounted to €107,520 for three months ended March 31, 2015, whilst no revenue was booked for the sales of Dialler test over the same period in 2014. We also reported on April 29, 2015 that as of March 31, 2015, our cash and cash equivalents amounted to €109.7 million, as compared with €114.6 million as of December 31, 2014. These amounts are preliminary in nature, have not been audited and are subject to change upon completion of audit for the full fiscal year 2015. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations for these periods.

Item 9. The Offer and Listing.**A. Offer and Listing Details.**

The ADS have been listed on Nasdaq 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. Our global offering in October 2014 was priced at \$21.64 per ADS or €34.00 per ordinary share on October 22, 2014. The following tables set forth for the periods indicated the reported high and low sale prices per ADS in U.S. dollars and per ordinary share on Euronext Paris in euros.

Nasdaq

	Per ADS	
	High	Low
Year Ended December 31, 2014:		
Fourth Quarter (beginning October 22)	\$28.50	\$22.20
Year Ended December 31, 2015:		
First Quarter	\$28.40	\$20.26
Month Ended:		
October 2014 (beginning October 22)	\$28.50	\$22.20
November 2014	\$25.98	\$23.20
December 2014	\$27.59	\$25.16
January 2015	\$28.40	\$24.00
February 2015	\$26.00	\$21.50
March 2015	\$24.07	\$20.26
April 2015 (through April 24, 2015)	\$27.99	\$23.02

[Table of Contents](#)

Euronext Paris

Period	High	Low
Annual		
2012	€ 9.74	€ 7.19
2013	€12.50	€ 7.51
2014	€44.88	€10.78
Quarterly		
First Quarter 2013	€ 9.75	€ 7.90
Second Quarter 2013	€ 8.79	€ 8.00
Third Quarter 2013	€ 8.28	€ 7.51
Fourth Quarter 2013	€12.50	€ 7.66
First Quarter 2014	€23.50	€10.78
Second Quarter 2014	€21.20	€14.61
Third Quarter 2014	€37.27	€18.37
Fourth Quarter 2014	€44.88	€32.01
First Quarter 2015	€47.23	€37.57
Month Ended		
October 2014	€41.43	€32.01
November 2014	€41.35	€37.28
December 2014	€44.88	€40.26
January 2015	€47.23	€41.40
February 2015	€42.85	€37.57
March 2015	€43.70	€37.65
April 2015 (through April 24, 2015)	€53.47	€42.07

On April 24, 2015, the last reported sale price of the ADSs on Nasdaq was \$26.29 per ADS, and the last reported sale price of the ordinary shares on Euronext Paris was €47.99 per share.

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 October 22, 2014, 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.

We entered into an underwriting agreement among Citigroup Global Markets Inc. and Leerink Partners LLC, as representatives of the underwriters, on October 22, 2014, with respect to the ADSs and ordinary shares sold in our global offering. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities. For additional information on our material contracts, please see Item 4 and Item 6 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. 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 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;

[Table of Contents](#)

- 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 the voting power or value 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 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 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.

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

[Table of Contents](#)

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 taxable 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

[Table of Contents](#)

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 not a controlled foreign corporation or are publicly traded for the entire year being tested, would be measured by 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. Although it is not free from doubt, based on the composition of our income for our 2014 taxable year, we believe that we were a PFIC for our 2014 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

[Table of Contents](#)

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 were 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 income 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 Gide Loyrette Nouel A.A.R.P.I., 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.

France has recently introduced a comprehensive set of new tax rules applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor's net assets for purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French 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 ADS 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 ADS 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

[Table of Contents](#)

Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, 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 0.2% 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. Nasdaq is not currently acknowledged by the French AMF but this may change in the future. 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.

Purchases of our securities may be subject to such tax provided that its market capitalization exceeds 1 billion euros and that Nasdaq is acknowledged by the French AMF.

In the case where Article 235 ter ZD of the FTC is not applicable, transfers of shares issued by a listed French company will 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 wealth tax (*impôt de solidarité sur la fortune*) applies only to individuals and does not generally apply to securities held by an eligible U.S. Holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that such U.S. Holder does not own directly or indirectly more than 25% of the issuer's financial rights.

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 30%. 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 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, will not be subject to this 30% or 75% withholding tax rate, but 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 who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose 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, is generally reduced to 15%, or to 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 complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. 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 of 5% or 15% provided that such 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 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 French tax authorities 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.

[Table of Contents](#)

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.

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 (other than redemption proceeds characterized as dividends under French domestic tax law or administrative guidelines), 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.

You may also review a copy of this Annual Report on Form 20-F, including exhibits and any schedule filed herewith, and obtain copies of such materials at prescribed rates, at the SEC's Public Reference Room in Room 1580, 100 F Street, NE, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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 DBV Technologies, 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 applicable.

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 2012, 2013 and 2014, less than 11%, 10% and 7%, respectively, of our purchases and other external expenses have been made in U.S. dollars, generating a negligible net annual foreign exchange loss of €1,502, €2,831 and €24,337, respectively, for those periods. In light of these insignificant amounts, we have not adopted, at this stage, a hedging mechanism in order to protect our business activity against fluctuations in exchange rates. We cannot rule out the possibility that a significant increase in our business, particularly in the United States, may result in greater exposure to exchange rate risk and would then consider adopting an appropriate policy for hedging against these risks.

Liquidity Risk

As of this date, we do not believe that we are exposed to a short-term (12 months) liquidity risk, considering the cash and cash equivalents that we have available as of December 31, 2014 of €114.6 million, which are mainly composed of cash and term deposits that are convertible into cash immediately without penalties in case of a need for cash.

Moreover, we believe that the net proceeds of the global offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements until the end of 2016.

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.

[Table of Contents](#)

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 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:

<i>Service</i>	<i>Fees</i>
• 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.

[Table of Contents](#)

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.

Global Offering

In October 2014, we sold 4,919,498 ADSs, each representing one-half of one ordinary share, nominal value €0.10, and 614,923 ordinary shares, in our global offering at a price of \$21.64 per ADS and €34.00 per share, for aggregate gross proceeds to us of approximately €104.5 million. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were approximately €93.7 million. The offering commenced on October 15, 2014 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-198870, for our global offering was October 21, 2014. Citigroup Global Markets Inc., Leerink Partners LLC and Bryan, Garnier & Co. are acting as joint global coordinators and joint book-running managers of the global offering.

A portion of the net proceeds from our global offering was used for general corporate purposes. The balance is held in cash and cash equivalents and is intended to also be used for general corporate purposes. None of the net proceeds of our global offering were paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

Item 15. Controls and Procedures.

Our chief executive officer (*principal executive officer*) and chief operating officer (*principal financial officer*), after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of December 31, 2014, have concluded that, as of such date, our disclosure controls and procedures were effective and ensured that information required to be disclosed by us in reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer (*principal executive officer*) and chief operating officer (*principal financial officer*), to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms.

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

There were no changes in our internal control over financial reporting that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 15T. Controls and Procedures.

Not applicable.

Item 16. Reserved.

Not applicable.

Item 16A. Audit Committees Financial Expert.

Our board of directors has determined that Dr. Bjerke 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. Dr. Bjerke 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.

[Table of Contents](#)**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. The Code of Conduct is available on our website at www.dbv-technologies.com. The audit committee of our board of directors will be responsible for overseeing the Code of Conduct and will be required to approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Item 16C. Principal Accountant Fees and Services.

Deloitte & Associés has served as our independent registered public accounting firm for 2013 and 2014. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	Year Ended December 31,	
	2014	2013
	(euro in thousands)	
Audit Fees	€ 884	€ 192
Audit-Related Fees	—	—
Tax Fees	—	—
Other Fees	—	—
Total	€ 884	€ 192

“Audit Fees” are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that generally the independent accountant provides, such as consents and assistance with and review of documents filed with the SEC. In 2014, “Audit Fees” also include fees billed for assurance and related services regarding our global offering.

“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 the principal accountant for tax compliance, tax advice and tax planning related services.

“Other Fees” are any additional amounts billed for products and services provided by the principal accountant.

There were no “Audit Related Fees,” “Tax Fees” or billed or paid during 2013 or 2014.

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 & Associés as described above and believes that they are compatible with maintaining Deloitte & Associés’s independence as our independent registered public accounting firm.

[Table of Contents](#)

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 will be 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 intend to rely on the certain exemptions for foreign private issuers and follow French corporate governance practices in lieu of the Nasdaq corporate governance rules, including that (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.

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 U.S. Securities Exchange Act of 1934, as amended, or 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 annual 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-53 of this Annual Report on Form 20-F.

Item 18. Financial Statements.

Not applicable.

Item 19. Exhibits.

The Exhibits listed in the Exhibit Index at the end of this Annual Report on Form 20-F are filed as Exhibits to this Annual Report on Form 20-F.

Index to Financial Statements

	Page
<u>Annual Financial Statements for the Years Ended December 31, 2012, 2013 and 2014:</u>	
Report of Deloitte & Associés, Independent Registered Public Accounting Firm	F-2
Statements of Consolidated Financial Position as of December 31, 2012, 2013 and 2014	F-3
Statements of Consolidated Income (Loss) for the Years Ended December 31, 2012, 2013 and 2014	F-4
Statement of Consolidated Comprehensive Income (Loss) for the Years Ended December 31, 2012, 2013 and 2014	F-5
Statements of Consolidated Cash Flows for the Years Ended December 31, 2012, 2013 and 2014	F-6
Statements of Changes in Consolidated Shareholders' Equity for the Years Ended December 31, 2012, 2013 and 2014	F-7
Notes to the Financial Statements	F-8

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of DBV Technologies SA
Paris, France

We have audited the accompanying statements of consolidated financial position of DBV Technologies SA and subsidiaries (the “Company”) as of December 31, 2012, 2013 and 2014, and the related statements of consolidated income (loss), consolidated comprehensive income (loss), changes in consolidated shareholders’ equity, and consolidated cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the consolidated financial position of DBV Technologies SA and subsidiaries as of December 31, 2012, 2013 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014, in conformity with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board.

/s/ Deloitte & Associés

Represented by Fabien Brovedani

Neuilly-sur-Seine, France
April 29, 2015

STATEMENTS OF CONSOLIDATED FINANCIAL POSITION

	Notes	Year Ended December 31,		
		2012 (1)	2013 (1)	2014
		€	€	€
ASSETS				
Non-current assets				
Intangible assets	4	14,012	63,007	28,835
Property, plant, and equipment	5	988,283	1,734,149	2,224,928
Other non-current financial assets	6	384,357	623,829	1,595,861
Total non-current assets		1,386,652	2,420,985	3,849,624
Current assets				
Inventories and work in progress	7	29,673	6,568	124,071
Customer accounts receivable and related receivables	8	92,875	182,900	136,112
Other current assets	8	3,117,487	4,222,796	6,722,563
Cash and cash equivalents	9	38,348,130	39,402,761	114,583,141
Total current assets		41,588,165	43,815,024	121,565,887
TOTAL ASSETS		42,974,817	46,236,009	125,415,511
LIABILITIES				
Shareholders' equity				
Share capital	10	1,340,815	1,508,830	1,916,066
Premiums related to the share capital		54,612,601	69,640,899	163,876,789
Reserves		(3,868,181)	(11,448,627)	(26,336,016)
Net profit (loss)		(12,912,100)	(19,306,416)	(24,011,880)
Total shareholders' equity		39,173,135	40,394,685	115,444,959
Non-current liabilities				
Long-term financial debt	11	376,651	1,316,533	3,888,170
Non-current provisions	12	254,941	290,695	530,732
Total non-current liabilities		631,592	1,607,228	4,418,902
Current liabilities				
Short-term financial debt	11	257,414	126,292	212,736
Bank overdrafts		519,499	—	27,956
Supplier accounts payable and related payables	13	977,724	1,497,289	1,874,629
Other current liabilities	13	1,415,453	2,610,515	3,436,329
Total current liabilities		3,170,090	4,234,096	5,551,650
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		42,974,817	46,236,009	125,415,511

(1) The statement of consolidated financial position as of December 31, 2012 and 2013 corresponds to DBV Technologies SA, as the Company had no consolidated subsidiary as of this date

The accompanying notes form an integral part of these consolidated financial statements.

STATEMENTS OF CONSOLIDATED INCOME (LOSS)

	Notes	Year Ended December 31,		
		2012 (1)	2013 (1)	2014
		€	€	€
Operating income				
Revenues	15	174,360	181,800	210,759
Other income	15	2,602,228	3,644,513	4,550,763
Total income		2,776,588	3,826,313	4,761,522
Operating expenses				
Cost of goods sold		82,958	102,366	136,296
Research and development	16/17	11,499,368	17,366,538	21,143,442
General and administration	16/17	4,598,699	6,309,750	8,117,664
Total Expenses		16,181,025	23,778,654	29,397,402
Operating profit (loss)		(13,404,437)	(19,952,340)	(24,635,880)
Financial revenues	18	517,54	670,234	727,239
Financial expenses	18	(25,208)	(24,310)	(103,239)
Financial Profit (loss)		492,337	645,925	624,000
Income tax	19	—	—	—
Net profit (loss)		(12,912,100)	(19,306,416)	(24,011,880)
Basic / Diluted earnings per share (€/share)	22	(1.05)	(1.42)	(1.49)

- (1) The statement of consolidated income (loss) as of December 31, 2012 and 2013 corresponds to DBV Technologies SA's, as the Company had no consolidated subsidiary as of this date

The accompanying notes form an integral part of these consolidated financial statements.

STATEMENTS OF CONSOLIDATED COMPREHENSIVE INCOME (LOSS)

	Year Ended December 31		
	2012 (1)	2013 (1)	2014
	€	€	€
Net profit (loss)	(12,912,100)	(19,306,416)	(24,011,880)
Actuarial gains and losses on employee benefits, net of corporate tax	(99,900)	53,266	(153,256)
Profit (loss) directly recognised in shareholders' equity	(99,900)	53,266	(153,256)
Other items in the total profit (loss) to be recycled subsequently to the net profit (loss)	—	—	(25,941)
Total Comprehensive Income/ (loss)	(13,012,000)	(19,253,150)	(24,191,077)

- (1) The statement of consolidated comprehensive income (loss) as of December 31, 2012 and 2013 corresponds to DBV Technologies SA, as the Company had no consolidated subsidiary as of this date

In accordance with IAS 1 *Presentation of Financial Statements* (2007) (IAS 1), the Group, as defined in Note 1, presents a combined statement of other elements of comprehensive income (loss).

The Group does not hold any financial assets available for sale and non-current financial assets are measured at historical cost which approximates fair value; therefore, no change in fair value is reflected in the statement of consolidated comprehensive income (loss).

The accompanying notes form an integral part of these consolidated financial statements.

STATEMENTS OF CONSOLIDATED CASH FLOWS

	Notes	2012 (1) €	2013 (1) €	2014 €
Cash flows from operating activities				
Net profit (loss) for the period		(12,912,100)	(19,306,416)	(24,011,880)
Reconciliation of net profit (or loss) and of the cash used for operating activities:				
Amortization and depreciation		281,543	341,176	515,389
Retirement pension obligations		36,495	89,572	86,781
Expenses related to share-based payments		3,194,308	5,048,201	4,639,403
Operating cash flows before change in working capital		(9,399,754)	(13,827,467)	(18,770,307)
Inventories and work in progress		4,776	23,105	(117,503)
Customer accounts receivable		(124,450)	(57,675)	(124,664)
Other receivables		(230,647)	(1,105,309)	(1,701,831)
Supplier accounts payable		(1,226,754)	519,565	(424,204)
Other current liabilities		544,280	1,194,565	578,857
Change in the working capital requirement		(1,032,794)	574,252	(1,789,345)
Net cash flow from operating activities		(10,432,549)	(13,253,215)	(20,559,652)
Cash flows from investment activities				
Acquisitions of property, plant, and equipment	5	(340,411)	(1,089,902)	(941,301)
Acquisitions of intangible assets	4	(21,024)	(81,385)	(30,695)
Acquisitions of non-current financial assets		(33,685)	(237,138)	(124,235)
Other cash flows related to investment transactions		26,360		
Net cash flows from investment activities		(368,760)	(1,408,425)	(1,096,231)
Cash flows from financing activities:				
Increase in conditional advances	11	14,613	1,068,760	3,128,000
(decrease) in conditional advances	11	(200,000)	(260,000)	(128,000)
Treasury shares		(278,291)	230,697	(888,977)
Capital increases, net of transaction costs	10	37,562,500	15,196,313	94,643,126
Other cash flows related to financing activities				54,157
Net cash flows from financing activities:		37,098,822	16,235,770	96,808,306
(Decrease)/Increase in cash		26,297,514	1,574,130	75,152,424
Net Cash and cash equivalents at the beginning of the period		11,531,117	37,828,631	39,402,761
Net Cash and cash equivalents at the close of the period	9	37,828,631	39,402,761	114,555,185

- (1) The statement of consolidated cash flows as of December 31, 2012 and 2013 corresponds to DBV Technologies SA's, as the Company had no consolidated subsidiary as of this date

The accompanying notes form an integral part of these consolidated financial statements.

STATEMENTS OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY
(Amounts in Euros)

	Share Capital Ordinary Shares		Premiums Related to the Share Capital	Reserves	Profit (loss)	Total Shareholders' Equity
	Number of shares	Amount				
At January 1, 2012 (1)	8,822,745	882,275	17,508,641	553,964	(7,238,262)	11,706,617
Net profit (loss)					(12,912,100)	(12,912,100)
Profit (loss) directly recognized in shareholders' equity				(99,900)		(99,900)
Total profit (loss) directly recognized in shareholders' equity				(99,900)	(12,912,100)	(13,012,000)
Allocation of prior period profit (loss)				(7,238,262)	7,238,262	
Increase in capital	4,585,402	458,54	37,095,400			37,553,940
Treasury shares		—		(278,291)		(278,291)
Issue of share warrants			8,560			8,560
Share-based payments				3,194,308		3,194,308
At December 31, 2012 (1)	13,408,147	1,340,815	54,612,601	(3,868,181)	(12,912,100)	39,173,135
Net profit (loss)					(19,306,416)	(19,306,416)
Profit (loss) directly recognized in shareholders' equity				53,266		53,266
Total profit (loss) directly recognized in shareholders' equity				53,266	(19,306,416)	(19,253,150)
Allocation of prior period profit (loss)				(12,912,100)	12,912,100	
Increase in capital	1,680,151	168,015	14,960,858			15,128,873
Treasury shares		—		230,697		230,697
Foreign exchange translation				(511)		(511)
Issue of share warrants			67,440			67,440
Share-based payments				5,048,201		5,048,201
At December 31, 2013 (1)	15,088,298	1,508,830	69,640,898	(11,448,627)	(19,306,416)	40,394,685
Net profit (loss)					(24,011,880)	(24,011,880)
Profit (loss) directly recognized in shareholders' equity				(179,197)		(179,197)
Total profit (loss) directly recognized in shareholders' equity				(179,197)	(24,011,880)	(24,191,077)
Allocation of prior period Income (Loss)				(19,306,416)	19,306,416	
Increase in capital	4,072,363	407,236	94,203,624			94,610,860
Treasury shares				(41,179)		(41,179)
Issue of share warrants			32,267			32,267
Share-based payments				4,639,403		4,639,403
At December 31, 2014	19,160,661	1,916,066	163,876,789	(26,336,016)	(24,011,880)	115,444,959

- (1) The statement of changes in consolidated shareholders' equity as of December 31, 2012 and 2013 corresponds to DBV Technologies SA's, as the Company had no consolidated subsidiary as of this date

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.

The Company markets a ready-to-use diagnostic product to detect the allergy to cow’s milk protein in children called Diallertest Milk, which was launched in France in 2004. This product is currently available with a temporary exception status from French regulatory authorities. Regulatory authorities have requested a pivotal phase III study to complete the marketing authorization file. The Company is currently assessing the relevance of conducting such a study and might decide, if necessary, to stop marketing Diallertest Milk.

Main events in 2014

On September 22, 2014, we announced topline results for our VIPES (Viaskin Peanut’s Efficacy and Safety) phase IIb clinical trial of Viaskin Peanut in peanut allergic patients. The trial met its primary endpoint at the highest explored dose (Viaskin Peanut 250 µg), achieving statistical significance ($p=0.0108$) in desensitizing a higher proportion of patients versus placebo after 12 months of Epicutaneous Immunotherapy (EPIT). Patients treated with Viaskin Peanut 250 µg also showed statistically significant changes in measured serological markers while placebo patients did not exhibit material differences. The safety profile was confirmed across all active arms with no serious treatment-related adverse events reported, and patient compliance with daily Viaskin Peanut application was above 97%. The trial drop-out rate was 6.4%, below the 15% rate initially anticipated. The VIPES trial is the largest clinical trial in peanut allergy desensitization ever completed, and full results of efficacy and safety will be presented at future scientific meetings.

Note 2: General Information and Statement of Compliance

Preliminary remarks

The company DBV Technologies Inc. was established on April 7, 2014. The share capital of this US subsidiary is 100% owned by DBV Technologies SA. These financial statements are the first annual consolidated financial statements of the group thus formed.

The financial information as at December 31, 2012 and 2013 corresponds to the information previously published and includes only the transactions related to the parent company DBV Technologies, which had no equity interest in a subsidiary over the periods in question.

General principles

The accompanying consolidated financial statements and related notes (the “Financial Statements”) present the operations of DBV Technologies SA and its subsidiary (the Group) as of December 31, 2014. The Company is a corporate venture under French law (*société anonyme*) and has its registered office located at 80/84 rue des Meuniers, 92220 Bagneux.

Our Financial Statements as of December 31, 2014 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 24, 2015.

All amounts are expressed in euros, unless stated otherwise.

For consolidation purposes, both DBV Technologies and its subsidiary DBV Technologies Inc. have prepared individual financial statements for the period ended December 31, 2014.

Statement of Compliance

Our Consolidated 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, 2014. Comparative figures are presented for December 31, 2012 and 2013.

Due to the listing of DBV Technologies S.A. ordinary shares on the Euronext Paris and in accordance with the European Union’s regulation No. 1606/2002 of July 19, 2002, the consolidated financial statements of the Group are prepared in accordance with IFRS, as adopted by the European Union (EU).

As of December 31, 2014, all IFRS that the IASB had published and that are mandatory are the same as those endorsed by the EU and mandatory in the EU, with the exception of IAS 39 *Financial Instruments: Recognition and Measurement* (revised December 2003), which the EU only partially adopted. The part not adopted by the EU has no impact on the Consolidated Financial Statements. As a result, the Consolidated Financial Statements comply with International Financial Reporting Standards 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 Consolidated Financial Statements are described below. These methods were used for all years presented.

The following new standards and amendments have been adopted by DBV Technologies from January 1, 2014 but have had no impact on the Consolidated Financial Statements:

- IFRIC 21 *Levies*, an interpretation of IAS 37 *Provisions, Contingent Liabilities and Contingent Assets*. The interpretation clarifies that the obligating event giving rise to a liability to pay a levy to a government agency is the activity that triggers the payment. IFRIC 21 has been applied retrospectively. The application of this interpretation has had no material impact on the disclosures or on the amounts recognized in the Group’s consolidated financial statements.

[Table of Contents](#)

- Amendments to IFRS 10, IFRS 12 and IAS 27 *Investment Entities*. The amendments to IFRS 10 define an investment entity and require a reporting entity that meets the definition of an investment entity not to consolidate its subsidiaries but instead to measure its subsidiaries at fair value through profit or loss in its consolidated and separate financial statements.
- Amendments to IAS 32 *Offsetting Financial Assets and Financial Liabilities*. The amendments to IAS 32 clarify the requirements relating to the offset of financial assets and financial liabilities. Specifically, the amendments clarify the meaning of “currently has a legally enforceable right of set-off” and “simultaneous realization and settlement”.
- Amendments to IAS 36 *Recoverable Amount Disclosures for Non-Financial Assets*. The amendments to IAS 36 remove the requirement to disclose the recoverable amount of a cash generating unit (CGU) to which goodwill or other intangible assets with indefinite useful lives had been allocated when there has been no impairment or reversal of impairment of the related CGU.
- Amendments to IAS 39 *Novation of Derivatives and Continuation of Hedge Accounting*. The amendments to IAS 39 provide relief from the requirement to discontinue hedge accounting when a derivative designated as a hedging instrument is novated under certain circumstances.

New and revised standards and amendments that may be relevant to the Company’s operations but are not yet effective. Management has not yet completed its assessment of these 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.

- IFRS 9 *Financial instruments*, effective for annual periods beginning on or after January 1, 2018
- IFRS 15 *Revenue from Contracts with Customers*, effective for annual periods beginning on or after January 1, 2017
- Amendments to IFRS 11 *Accounting for Acquisitions of Interests in Joint Operations*, effective for annual periods beginning on or after January 1, 2016
- Amendments to IAS 16 and IAS 38 *Clarification of Acceptable Methods of Depreciation and amortisation*, effective for annual periods beginning on or after January 1, 2016
- Amendments to IAS 19 *Defined Benefit Plans: Employee Contributions*, effective for annual periods beginning on or after July 1, 2014
- Amendments to IFRSs Annual Improvements to IFRSs 2010-2012 Cycle, effective for annual periods beginning on or after July 1, 2014
- Amendments to IFRSs Annual Improvements to IFRSs 2011-2013 Cycle, effective for annual periods beginning on or after July 1, 2014

The accounting policies and measurement principles adopted for the consolidated financial statements as of and for the year ended December 31, 2014 are the same as those used as of and for the years ended December 31, 2012 and 2013.

Note 3: Accounting Principles

Methods of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities 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.

[Table of Contents](#)

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 recognised 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 Currency Units 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 posted as assets on the statement 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 consolidated 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 Marketing 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 posted at their acquisition cost or, if applicable, at their production cost.

[Table of Contents](#)

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:

<u>PROPERTY, PLANT, AND EQUIPMENT ITEM</u>	<u>DEPRECIATION PERIOD</u>
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	10 years

3.3 Financial Assets

Financial assets include assets available for sale, assets owned until their maturity, loans and accounts receivable, and cash and cash equivalents.

The valuation and the accounting treatment of the financial assets and liabilities are defined by IAS 39 *Financial Instruments: Recognition and Measurement* ("IAS 39").

Assets Owned Until Their Maturity

These securities are exclusively fixed income or determinable income and have fixed maturities, other than loans and accounts receivable, that the company has the intention and the ability to keep until maturity. After their initial posting at their fair value, they are valued and posted to the accounts at the cost amortized on the basis of the effective interest rate ("EIR") method.

The assets owned until their maturity are monitored for any objective indication of impairment. A financial asset is impaired if its book value is greater than its recoverable amount as estimated during impairment tests. The impairment is posted to the income statement.

Loans and Receivables

This category includes other loans and accounts receivable and commercial receivables.

These instruments are initially posted to the accounts at their fair value and then at the amortized cost calculated with the EIR method. The short-term receivables without an interest rate are valued at the amount of the original invoice unless the application of an implicit interest rate has a significant effect. For the loans and variable-rate accounts receivable, a periodic re-estimation of the cash flows, in order to reflect the change in the market interest rate, modifies the effective interest rate and therefore the valuation of the loan or of the receivable.

The loans and receivables are monitored for any objective indication of impairment. A financial asset is impaired if its book value is greater than its recoverable amount as estimated during impairment tests. The impairment is posted to the income statement.

The loans and receivables also include the deposits and guarantees, which are classified under "Non-current financial assets" on the statement of financial position.

Assets at Fair Value Per the Income Statement

The assets considered to be held for trading purposes include the assets that the Company intends to resell in the near future in order to realize a capital gain, which is part of a portfolio of financial instruments managed together for which there exists a practice of selling in the short term. The assets held for trading may also include assets voluntarily classified in this category, in a manner that is independent of the criteria listed above ("fair value" option).

Assets Available for Sale

The assets available for sale include, primarily, securities that do not meet the criteria of the definition of the other categories of financial assets. They are valued at their fair value, and the changes in value are posted to shareholders' equity.

[Table of Contents](#)

The fair value corresponds to the market price for those securities that are listed on the stock exchange or to an estimate of the use value for unlisted securities, determined on the basis of the financial criteria most appropriate for the specific situation of each security. When there is an objective indication of the impairment of these securities, the accumulated impairment that has been posted to shareholders' equity is recognized in the income statement.

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 posted to the accounts at their cost or at their net liquidation value, if the latter is lower. In the latter case, the impairment is posted to income or loss. The inventories are valued on the basis of the "first-in, first-out" ("FIFO") method.

3.6 Cash and Cash Equivalents

Cash equivalents are owned for the purpose of meeting short-term cash commitments rather than for the objective of investment or for other purposes. They are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. Cash and cash equivalents are constituted by liquid assets that are available immediately, long-term investments that can be liquidated immediately without a penalty, and investment securities. They are valued on the basis of the IAS 39 categories under which they fall.

Investment securities are readily convertible into a known amount of cash and are subject to a negligible risk of change in value. They are valued at their fair value, and the changes in value are posted to the financial income or loss. Given the nature of these assets, their fair value is generally close to their net carrying value.

3.7 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 posted to the books under shareholders' equity as a deduction from the revenue from the issue, net of tax.

3.8 Payments in Shares

Since its formation, 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 enjoyed from the equity instruments are acquired.

The Company has applied IFRS 2 to all equity instruments granted since 2002 to its employees, members of the Board of Directors, other individuals, or to companies.

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

Financial Liabilities at Amortized Cost

Borrowings and other financial liabilities are valued initially at their fair value and then at the amortized cost, calculated on the basis of the effective interest rate ("EIR") method.

The transaction expenses that are directly attributable to the acquisition or to the issue of a financial liability reduce that financial liability. These expenses are then amortized over the lifetime of the liability, on the basis of the EIR.

[Table of Contents](#)

The EIR is the rate that equalizes the anticipated flow of future cash outflows with the current net book value of the financial liability in order to deduct its amortized cost therefrom.

Liabilities at Fair Value per the Income Statement

The liabilities at fair value per the income statement are valued at their fair value.

3.10 Subsidies and Conditional Advances

Subsidies

The Company receives from time to time 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 COFACE advances presented in Note 11.1.

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 posted to 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).

[Table of Contents](#)

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 income statement 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 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

The sales revenue of the Company results mainly from the sale of the product *Diallertest*, a kit for diagnosing the allergy to proteins in cow's milk.

The Company recognizes revenue when the amount can be measured reliably, when it is likely that the future economic advantages will benefit the Company, and when the specific criteria are met for the business activity of the Company. For the product sales, the sales revenue is recognized upon delivery.

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.

These subsidies are recognized as "Other income" for the fiscal year that recorded the corresponding expenses or expenditures, when obtaining the subsidy is reasonably certain.

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 since it was formed.

The Company received the reimbursement of the Research Tax Credit for the year 2012 for an amount of €2.5 million during the year 2013.

The Company received the reimbursement of the Research Tax Credit for the year 2013 for an amount of €3.3 million during the year 2014. It will request the reimbursement of the 2014 Research Tax Credit under the Community tax rules for small and medium firms in compliance with the regulatory texts in effect.

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 posted to 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 statement 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 loss realized are primarily located in France.

3.17 Other Items in the Comprehensive Profit (or Loss)

The revenue and expense items for the period that are not posted to the income statement as stipulated by the applicable standards are presented, as necessary, under the rubric "Other items in the comprehensive profit (or loss)."

3.18 Use of Estimates

Our Financial Statements are prepared in accordance with IFRS. The preparation of our Financial Statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

These estimates and judgments involve mainly:

- 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;
- estimation of the repayments of the conditional advances obtained by Company from public institutions. The anticipated repayments of the conditional advances are analysed at each reporting period.

[Table of Contents](#)

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 Events After the Close of the Fiscal Year

The statement of financial position and the income statement 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:

	2012	2013	2014
	(Amounts in Euros)		
Patents, licenses, trademarks	29,848	31,080	45,793
Software	66,172	146,325	162,307
Total historical cost	96,020	177,405	208,100
Accumulated amort. of patents, licenses, and trademarks	29,848	30,020	38,624
Accumulated depreciation of software packages	52,160	84,378	140,641
Accumulated amortization and depreciation	82,008	114,398	179,265
Net total	14,012	63,007	28,835

There has been no recognition of impairment losses in application of IAS 36 *Impairment of Assets* over the fiscal years presented.

Note 5: Property, Plant, and Equipment

	01/01/2012	Increase	Decrease	12/31/2012
	(Amounts in Euros)			
Laboratory equipment	676,795	104,507	—	781,302
Building fixtures	466,109	164,227	—	630,336
Office equipment	116,962	14,996	—	131,958
Computer equipment	143,334	56,681	—	200,015
Other property, plant, and equipment	48	—	—	48
Total, gross	1,403,247	340,411	—	1,743,658
Accumulated depreciation of laboratory equipment	403,262	102,974	—	506,236
Accumulated depreciation of the building fixtures	21,447	57,030	—	78,477
Accumulated depreciation of office equipment	43,143	15,888	—	59,031
Accumulated depreciation of computer equipment	86,156	25,427	—	111,583
Accumulated depreciation of other property, plant, and equipment	48	—	—	48
Total accumulated amortization and depreciation	554,056	201,319	—	755,375
Total, net	849,191	139,093	—	988,284

[Table of Contents](#)

	01/01/2013	Increase	Decrease	12/31/2013
	(Amounts in Euros)			
Laboratory equipment	781,302	590,306	—	1,371,607
Building fixtures	630,336	291,890	—	922,226
Office equipment	131,958	83,010	—	214,968
Computer equipment	200,015	74,127	—	274,141
Other property, plant, and equipment	48	50,570	—	50,618
Total, gross	1,743,659	1,089,902	—	2,833,560
Accumulated depreciation of laboratory equipment	506,236	163,717	—	669,953
Accumulated depreciation of the building fixtures	78,477	100,044	—	178,520
Accumulated depreciation of office equipment	59,031	33,066	—	92,097
Accumulated depreciation of computer equipment	111,583	47,195	—	158,779
Accumulated depreciation of other property, plant, and equipment	48	—	—	48
Total accumulated amortization and depreciation	755,375	344,023	—	1,099,397
Total, net	988,284	745,879	—	1,734,163

	01/01/2014	Increase	Decrease	12/31/2014
	(Amounts in Euros)			
Laboratory equipment	1,371,607	885,680	—	2,257,287
Building fixtures	922,226	7,702	—	929,928
Office equipment	214,968	—	—	214,968
Computer equipment	274,141	47,919	—	322,060
Other property, plant, and equipment	50,618	—	48	50,570
Total, gross	2,833,560	941,301	48	3,774,813
Accumulated depreciation of laboratory equipment	669,953	245,716	—	915,669
Accumulated depreciation of the building fixtures	178,520	107,367	—	285,887
Accumulated depreciation of office equipment	92,097	33,806	—	125,903
Accumulated depreciation of computer equipment	158,779	63,647	—	222,426
Accumulated depreciation of other property, plant, and equipment	48	—	48	—
Total accumulated amortization and depreciation	1,099,397	450,522	48	1,549,885
Total, net	1,734,163	490,779	—	2,224,928

[Table of Contents](#)

Over the two fiscal years presented, the acquisitions correspond primarily to building fixtures and to laboratory and production equipment and material. The increase in the building fixtures item is related to the improvements made in the Company's new premises based in Bagneux, France.

Note 6: Non-Current Financial Assets

	2012	2013	2014
	(Amounts in Euros)		
Deposits	82,999	82,342	99,825
Pledged securities	275,510	278,057	384,809
Liquidity contract	25,848	263,430	1,111,227
Total non-current financial assets	384,357	623,829	1,595,861

The non-current financial assets are composed of security deposits paid to the lessor and of open-ended mutual funds (*sociétés d'investissement à capital variable* "SICAVs") pledged as guarantees of the ordinary rental agreements and the liquidity contract. Under the liquidity contract, 8,054 treasury shares were allocated for the reduction of shareholders' equity as at December 31, 2014 with the cash balance being maintained in financial assets. The share capital is divided in 19,160,661 shares including these 8,054 treasury shares.

On March 31, 2014, DBV Technologies announced an additional contribution of €300,000 to the liquidity agreement held by Natixis in accordance with the Charter of Ethics established by the AMAFI of March 8, 2011 and approved by the Autorité des Marchés Financiers.

On December 15, 2014, DBV Technologies announced an additional contribution of €600,000 to the liquidity agreement held by Natixis in accordance with the Charter of Ethics established by the AMAFI of March 8, 2011 and approved by the Autorité des Marchés Financiers.

Note 7: Inventories and Work in Progress

	2012	2013	2014
	(Amounts in Euros)		
Inventories of raw materials	28,023	6,568	124,071
Depreciation of inventories and work in progress	1,650	—	—
Total net value of the inventories and work in progress	29,673	6,568	124,071

The inventories and work in progress involve the Diallertest product.

Note 8: Customer Accounts Receivable and Other Current Assets

8.1 Customer Accounts Receivable and Related Receivables

	2012	2013	2014
	(Amounts in Euros)		
Accounts receivable and related receivables	138,322	195,997	149,209
Valuation allowance (charged to income statement)	(45,447)	(13,097)	(13,097)
Total net value of accounts receivable	92,875	182,900	136,112

Table of Contents

All the customer accounts receivable have payment terms of less than one year.

Accounts receivable and related receivables relate primarily to the sales of Diallertest.

Description— 2014	Balance at beginning of period	Additions		Reversal	Balance at end of period
		Charged to Income statement	Charged to Other accounts		
Valuation allowance deducted from account receivables	13,097	—	—	—	13,097

Description—2013	Balance at beginning of period	Additions		Reversal	Balance at end of period
		Charged to Income statement	Charged to Other accounts		
Valuation allowance deducted from Account receivables	45,447	—	—	32,350	13,097

Description—2012	Balance at beginning of period	Additions		Reversal	Balance at end of period
		Charged to costs and expenses	Charged to Other accounts		
Valuation allowance deducted from Account receivables	13,097	32,350	—	—	45,447

The valuation allowance of €32,350 posted in 2012 has been reversed in 2013 (and classified as a deduction of general and administrative expenses) following receipt of the corresponding payment. It explains the decrease in depreciation of accounts receivable in 2013.

8.2 Other current assets

The other current assets are broken down as follows:

	2012	2013 (Amounts in Euros)	2014
Research tax credit	2,522,399	3,312,462	4,339,620
Other tax claims	355,728	594,723	1 022,563
Other receivables	45,664	—	422,516
Prepaid expenses	193,696	315,611	937,864
Total	3,117,487	4,222,796	6,722,563

The other tax debt claims are primarily related to the deductible VAT as well as the reimbursement of VAT that has been requested.

As at December 31, 2013, prepaid expenses are comprised primarily of rental and insurance expenses, as well as legal and scientific consulting fees.

As at December 31, 2014, prepaid expenses are comprised primarily of rental and insurance expenses, as well as legal and scientific consulting fees.

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 3.14, the Research Tax Credit is posted to the accounts as “other income” during the year with which the eligible research expenditures are associated.

[Table of Contents](#)

The changes in this Research Tax Credit over the last three fiscal years are presented as follows:

	Amounts in Euros
Opening balance sheet receivable as of January 1, 2012	1,707,572
+ Operating revenue	2,522,399
- Payment received	(1,699,080)
- Adjustment	(8,492)
Closing balance sheet receivable as of December 31, 2012	2,522,399

	Amounts in Euros
Opening balance sheet receivable as of January 1, 2013	2,522,399
+ Operating revenue	3,312,462
- Payment received	(2,473,045)
- Adjustment	(49,354)
Closing balance sheet receivable as of December 31, 2013	3,312,462

	Amounts in Euros
Opening Balance Sheet Receivable as of January 1, 2014	3,312,462
+ Operating revenue	4,339,620
- Payment received	(3,312,462)
Closing Balance Sheet Receivable as of December 31, 2014	4,339,620

The adjustments to the amount of the receivable reflect the penalties related to the fiscal verification of the Research Tax Credit 2012 that occurred in 2013.

Note 9: Cash and Cash Equivalents

The cash and cash equivalents item is broken down as follows (in Euros):

	2012	2013	2014
	(Amounts in Euros)		
Cash	1,085	826,154	107,690
Cash equivalents: term deposits	38,347,045	38,576,607	114,475,451
Total cash and cash equivalent as reported in statement of financial position	38,348,130	39,402,761	114,583,141
Bank overdrafts	(519,499)	—	(27,956)
Total net cash and cash equivalents as reported in the statement of cash flow	37,828,631	39,402,761	114,555,185

[Table of Contents](#)

Term deposits are immediately convertible into cash at no cost. They are measured using level 1 fair value measurements. The increase in cash and cash equivalents mainly relates to the net proceeds received as part of our initial public offering that was completed in October 2014.

Note 10: Capital

10.1 Share Capital Issued

The share capital, as of December 31, 2014, is set at the sum of €1,916,066.10. It is divided into 19,160,661 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 at December 31 2012, December 31 2013 and 2014:

Date	Nature of the Transactions	Share Capital	Share premium	Number of Shares	Nominal value
	Balance as of January 1, 2012	€ 882,274.50	€17,508,641.11	8,822,745	€ 0.10
01/17/2012 and 09/25/2012	Issue of share subscription warrants		€ 8,560		
03/28/2012	Capital increase by issuance of common shares	€ 457,317.10	€36,988,256.33	4,573,171	
04/26/2012	Capital increase by issuance of common shares	€ 1,223.10	€ 107,143.56	12,231	
	Balance as of December 31, 2012	€1,340,814.70	€54,612,601.00	13,408,147	€ 0.10

Date	Nature of the Transactions	Share Capital	Share premium	Number of Shares	Nominal value
	Balance as of January 1, 2013	€1 340,814.70	€54,612,601.00	13,408,147	€ 0.10
07/25/2013	Issue of share subscription warrants		€ 67,440.00		
11/14/2013	Capital increase by issuance of common shares	€ 168,015.10	€14,960,857.70	1,680,151	
	Balance as of December 31, 2013	€1,508,829.80	€69,640,898.70	15,088,298	€ 0.10

[Table of Contents](#)

Date	Nature of the Transactions	Share Capital	Share premium	Number of Shares	Nominal value
	Balance as of January 1, 2014	€1,508,829.80	€ 69,640,898.70	15,088,298	€ 0.10
01/23/2014	Capital increase by issuance of common shares	€ 3,765.00	€ 189,379.50	37,650	
02/11/2014	Capital increase by issuance of common shares	€ 500.00	€ 41,225.00	5,000	
04/02/2014	Capital increase by incorporation of reserve	€ 24,248.40	€ (24,248.40)	242,484	
06/11/2014	Capital increase by issuance of common shares	€ 4,500.00	€ 226,350.00	45,000	
06/13/2014	Capital increase by issuance of common shares	€ 4,000.50	€ 169,221.15	40,005	
06/18/2014	Capital increase by issuance of common shares	€ 975.00	€ 44,557.50	9,750	
06/19/2014	Capital increase by issuance of common shares	€ 100.50	€ 5,055.15	1,005	
07/25/2014	Capital increase by incorporation of reserve	€ 4,469.30	€ (4,469.30)	44,693	
09/19/2014	Capital increase by incorporation of reserve	€ 25,741.80	€ (25,741.80)	257,418	
10/03/2014	Capital increase by issuance of common shares	€ 2,296.50	€ 104,950.05	22,965	
10/22/2014	Capital increase by issuance of common shares	€ 307,468.60	€104,231,855.40	3,074,686	
11/01/2014	Capital increase by incorporation of reserve	€ 25,742.20	€ (25,742.20)	257,422	
11/30/2014	Capital increase by issuance of common shares	€ 1,756.00	€ 96,976.80	17,560	
11/30/2014	Capital increase by issuance of common shares	€ 1,672.50	€ 83,333.25	16,725	
12/31/2014	Issue of share subscription warrants		€ 32,266.55		
12/31/2014	Fees charged to share premium 2014		€ (10,909,078.52)		
	Balance as of December 31, 2014	€1,916,066.10	€163,876,788.83	19,160,661	€ 0.10

The fees and banks commissions related to share capital increases were posted in deduction of the share premium, amounting to €10,909,078.52

Initial public offering on the NASDAQ Global Market

On October 22, 2014, DBV Technologies announced the pricing of its global offering of 2,673,641 common shares, of which 2,138,913 ordinary shares represented by 4,277,826 American Depositary Shares (ADS) at the subscription price of \$ 21.64 per ADS, as part of a public offering conducted in the United States, Canada and some countries outside of France, and 534,728 common shares at a price of € 34 per share, under a concurrent private placement conducted by leaders banks and international sales agents in France and in some countries outside the United States and Canada.

As part of the initial public offering completed in October 2014, share capital increased by the issuance of 3,074,686 shares €(307,468.60) with a corresponding increase of €93,403,561.17 in share premium (€104,231,855.40 gross, or €93,403,561.17 net after deduction of fees and expenses for €10,828,294.23).

[Table of Contents](#)

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 12/31/2012	Number of warrants null and void as of 12/31/2012	Number of warrants null and outstanding as of 12/31/2012	Maximum number of shares to be issued	Strike price per share
12/23/2005	BSA/BSPCE	17,115	17,115	—	—	€ —
12/07/2007	BSA	1,717	572	1,145	17,175	€ 4.33
01/21/2009	BSA/BSPCE	16,380	—	16,380	245,700	€ 4.33
01/21/2009	BSPCE	2,296	—	2,296	34,440	€ 4.33
06/25/2010	BSA	1,825	—	1,825	27,375	€ 4.33
01/28/2011	BSA	10,039	7,529	2,510	37,650	€ 5.13
06/24/2011	BSA/BSPCE	32,000	—	32,000	480,000	€ 5.13
11/22/2011	BSA/BSPCE	11,377	—	11,377	170,655	€ 5.13
01/17/2012	BSA	89,835	—	89,835	89,835	€ 5.13
04/02/2012	AGA	669,796	—	669,796	669,796	€ —
07/25/2012	AGA	134,081	—	134,081	134,081	€ —
09/25/2012	BSA	30,000	—	30,000	30,000	€ 8.59
11/28/2012	AGA	35,360	—	35,360	35,360	€ —
Total		1,051,821	25,216	1,026,605	1,972,067	

Date	Type	Number of warrants issued as of 12/31/2013	Number of warrants null and void as of 12/31/2013	Number of warrants outstanding as of 12/31/2013	Maximum number of shares to be issued	Strike price per share
12/07/2007	BSA	1,717	572	1,145	17,175	€ 4.33
01/21/2009	BSA/BSPCE	16,380	—	16,380	245,700	€ 4.33
01/21/2009	BSPCE	2,296	—	2,296	34,440	€ 4.33
06/25/2010	BSA	1,825	—	1,825	27,375	€ 4.33
01/28/2011	BSA	10,039	7,529	2,510	37,650	€ 5.13
06/24/2011	BSA/BSPCE	32,000	—	32,000	480,000	€ 5.13
11/22/2011	BSA/BSPCE	11,377	—	11,377	170,655	€ 5.13
01/17/2012	BSA	89,835	—	89,835	89,835	€ 5.13
04/02/2012	AGA	669,796	—	669,796	669,796	€ —
07/25/2012	AGA	134,081	—	134,081	134,081	€ —
09/25/2012	BSA	30,000	—	30,000	30,000	€ 8.59
11/28/2012	AGA	35,360	—	35,360	35,360	€ —
07/25/2013	BSA	73,000	—	73,000	73,000	€ 8.10
09/12/2013	AGA	501,500	—	501,500	501,500	€ —
09/18/2013	SO	518,000	—	518,000	518,000	€ 7.57
Total		2,127,206	8,101	2,119,105	3,064,567	

Date	Type	Number of warrants issued as of 12/31/2014	Number of warrants null and void as of 12/31/2014	Number of warrants null and outstanding as of 12/31/2014	Maximum number of shares to be issued	Strike price per share
12/07/2007	BSA	1,717	572	1,145	17,175	€ 4.33
01/21/2009	BSA/BSPCE	16,380	—	13,713	205,695	€ 4.33
01/21/2009	BSPCE	2,296	—	—	—	€ 4.33
06/25/2010	BSA	1,825	—	1,825	27,375	€ 4.33
01/28/2011	BSA	10,039	7,529	—	—	€ 5.13
06/24/2011	BSA/BSPCE	32,000	—	28,933	433,995	€ 5.13
11/22/2011	BSA/BSPCE	11,377	—	9,373	140,595	€ 5.13
01/17/2012	BSA	89,835	—	89,835	89,835	€ 5.13
04/02/2012	AGA	669,796	—	—	—	€ —
07/25/2012	AGA	134,081	—	—	—	€ —
09/25/2012	BSA	30,000	—	25,000	25,000	€ 8.59
11/28/2012	AGA	35,360	—	35,360	35,360	€ —
07/25/2013	BSA	73,000	—	70,500	70,500	€ 8.10
09/12/2013	AGA	501,500	—	420,000	420,000	€ —
09/18/2013	SO	518,000	—	471,000	471,000	€ 7.57
06/03/2014	BSA	10,000	—	10,000	10,000	€ 18.79
06/03/2014	AGA	186,000	—	186,000	186,000	€ —
06/03/2014	SO	75,000	—	75,000	75,000	€ 19.01
Total		<u>2,398,206</u>	<u>8,101</u>	<u>1,437,684</u>	<u>2,207,530</u>	

[Table of Contents](#)

The total presented above does 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 Liabilities

11.1 Conditional Advances

The conditional advances from public institutions are subject to contracts with OSEO and COFACE.

As of December 31, 2012, the Company had two advance contracts with OSEO Innovation and a contract with COFACE. As of December 31, 2013, the Company had three advance contracts with OSEO Innovation and a contract with COFACE. As of December 31, 2014, the Company had two advance contracts with OSEO Innovation and a contract with COFACE.

These advances do not bear interest and are 100% repayable at their nominal value in the event of technical and/or commercial success.

The Company also benefited from a third grant from BpiFrance Financement in November 2014.

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 (amounts in Euros):

	<u>2nd OSEO advance</u>	<u>3rd OSEO advance</u>	<u>4th OSEO advance</u>	<u>COFACE</u>	<u>Total</u>
Opening Balance Sheet Debt as of 1/1/2012	450,713	246,238	—	122,501	819,452
+ receipts	—	—	—	—	—
- repayments	(200,000)	—	—	—	(200,000)
+/- other transactions	6,701	3,661	—	4,251	14,613
Opening Balance Sheet Debt as of 12/31/2012	257,414	249,899	—	126,752	634,065
Of which:					
Non-current portion					376,651
Current portion					257,414

[Table of Contents](#)

	2nd OSEO advance	3rd OSEO advance	4th OSEO advance	COFACE	Total
Opening Balance Sheet Debt as of 1/1/2013	257,414	249,899	—	126,752	634,065
+ receipts	—	256,000	903,500	—	1,159,500
- repayments	(260,000)	—	—	—	(260,000)
+/- other transactions	2,586	(1,579)	(111,047)	19,300	(90,740)
Opening Balance Sheet Debt as of 12/31/2013		504,320	792,453	146,052	1,442,825
Of which:					
Non-current portion					1,316,533
Current portion					126,292

	3rd OSEO advance	4th OSEO advance	BPI advance	COFACE	Total
Opening Balance Sheet Debt as of 1/1/2014	504,320	792,453	—	146,052	1,442,825
+ receipts	128,000	—	3,000,000	—	3,128,000
- repayments	(128,000)	—	—	—	(128,000)
+/- other transactions	2,276	12,932	(416,361)	4,994	(396,159)
Opening Balance Sheet Debt as of 12/31/2014	506,596	805,385	2,583,639	151,046	4,046,666
Of which:					
Non-current portion					3,854,666
Current portion					192,000
Stated interest rate	None	2.05%	None	None	
Discount rate	0.4%-1.9%	1.5%-1.8%	3.2%	4.25%	
Maturity (in years)	0-3	7-9	2-7	—	

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

Second OSEO Advance

On January 10, 2005, DBV Technologies obtained from OSEO a repayable financial assistance for innovation in the amount of €600,000 for a project to design a high-speed prototype machine for the production and development of second-generation patches intended for the detection of various allergies. The principal steps of this advance are the following:

- €300,000 were paid to the Company in 2005 upon the signing of the contract;
- €180,000 were paid to the Company in 2008;
- the balance of €120,000 was received in 2010.

The terms of repayment are the following:

- the first repayment of €140,000 made in 2011;
- the second repayment in the amount of €200,000 made in 2012;
- the third and final repayment in the amount of €260,000 made in 2013.

[Table of Contents](#)

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 of treatment of the allergy to proteins in cow's milk.

The amount of the assistance will be paid as follows:

- €256,000 after the contract was signed;
- €256,000 from June 30, 2012 upon a call for funds;
- the balance of €128,000 after confirmation of the end of the programme notified on December 31, 2013.

The first payment of €256,000 was received in 2011.

The second payment of €256,000 was received in 2013.

The final balance of €128,000 has been received in 2014.

In the event of technical or commercial success of the program, the repayment schedule will be the following:

- €64,000 no later than September 30, 2014;
- €64,000 no later than December 31, 2014;
- €64,000 no later than March 31, 2015;
- €64,000 no later than June 30, 2015;
- €32,000 no later than September 30, 2015;
- €32,000 no later than December 31, 2015;
- €32,000 no later than March 31, 2016;
- €32,000 no later than June 30, 2016;
- €32,000 no later than September 30, 2016;
- €32,000 no later than December 31, 2016;
- €32,000 no later than March 31, 2017;
- €32,000 no later than June 30, 2017;
- €32,000 no later than September 30, 2017;
- €32,000 no later than December 31, 2017;
- €32,000 no later than March 31, 2018;
- €32,000 no later than June 30, 2018.

Regardless of the outcome of the development program, a fixed sum of €256,000 must be repaid in four quarterly instalments of €64,000 beginning on September 30, 2014.

[Table of Contents](#)

Fourth OSEO Advance

In 2013, OSEO has provided assistance in the form of conditional advances for €3,206,162 to DBV Technologies 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;
- €918,000 in October 2015;
- €481,162 in April 2018.

The funds of October 2014, were finally received on January 22, 2015 for an amount of €864,989.

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.

Furthermore, the financing program includes additional payment by OSEO to the company for a total of €1,919,056 in non-refundable subsidies.

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 schedule is as follows:

- €150,000 on June 30, 2017;
- €150,000 on September 30, 2017;
- €150,000 on December 31, 2017;
- €150,000 on March 31, 2018;
- €150,000 on June 30, 2018;
- €150,000 on Septembre 30, 2018;
- €150,000 on Decembre 31, 2018;
- €150,000 on March 31, 2019;
- €150,000 on June 30, 2019;
- €150,000 on Septembre 30, 2019;
- €150,000 on Decembre 31, 2019;
- €150,000 on March 31, 2020;
- €150,000 on June 30, 2020;
- €150,000 on September 30, 2020;
- €150,000 on Decembre 31, 2020;
- €150,000 on March 31, 2021;

[Table of Contents](#)

- €150,000 on June 30, 2021;
- €150,000 on September 30, 2021;
- €150,000 on December 31, 2021;
- €150,000 on March 31, 2022;

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 €147,534. 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. As of December 31, 2014, the amount that remained to be repaid under this advance amounted to €145,760 (€146,040 as of December 31, 2013).

The accounting treatment resulting from any changes in the anticipated flow of repayments of this advance is described in Note 3.11.

11.2 Due Dates of the Financial Liabilities

Due dates of the financial liabilities posted as of December 31, 2012

	Gross Amount	Less than One Year	One to Five Years	More than Five Years
	(Amounts in Euros)			
Financial liabilities				
Non-current conditional advances	376,651	—	376,651	—
Current conditional advances	257,414	257,414	—	—
Bank overdrafts	519,499	519,499	—	—
Supplier accounts payable and related payables	977,724	977,724	—	—
Total financial liabilities	2,131,288	1,754,637	376,651	—

Due dates of the financial liabilities recognized as of December 31, 2013

	Gross Amount	Less than One Year	One to Five Years	More than Five Years
	(Amounts in Euros)			
Financial liabilities				
Non-current conditional advances	1,316,531	—	524,080	792,453
Current conditional advances	126,292	126,292	—	—
Supplier accounts payable and related payables	1,497,289	1,497,289	—	—
Total financial liabilities	2,940,114	1,623,581	524,080	792,453

As detailed in Note 13, other current liabilities are primarily social security and tax liabilities and are mainly due in less than one year from the reporting date.

[Table of Contents](#)

Due dates of the financial liabilities recognized as of December 31, 2014

	Gross Amount	Less than One Year	One to Five Years	More than Five Years
(Amounts in Euros)				
Financial liabilities				
Non-current conditional advances	3,854,666	—	1,940,400	1,914,266
Non-current financial rent debts	33,504		33,504	
Current conditional advances	192,000	192,000	—	—
Current financial rent debts	20,653	20,653		
Accrued interest	83	83		
Supplier accounts payable and related payables	1,874,629	1,874,629		
Total financial liabilities	5,975,535	2,087,365	1,973,904	1,914,266

As detailed in Note 13, other current liabilities are primarily social security and tax liabilities and are mainly due in less than one year from the reporting date.

Note 12: Non-Current Provisions

	2012	2013	2014
(Amounts in Euros)			
Pension retirement obligations	254,389	290,695	530,732
Total	254,941	290,695	530,732

Commitments for Compensation Payable to Employees Upon Their Retirement

	Amounts in Euros
As of January 1, 2012	(117,994)
Costs of services rendered (operating expense)	(32,367)
Interest expense	(4,128)
Benefit paid	—
Actuarial losses	(99,900)
As of December 31, 2012	(254,389)
	Amounts in Euros
As of January 1, 2013	(254,389)
Costs of services rendered (operating expense)	(83,594)
Interest expense (finance expense)	(5,978)
Benefit paid	—
Actuarial losses	53,266
As of December 31, 2013	(290,695)
Costs of services rendered (operating expense)	(74,731)
Interest expense (finance expense)	(12,050)
Benefit paid	—
Actuarial gains	(153,256)
As of December 31, 2014	(530,732)

[Table of Contents](#)

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

	2012	2013	2014
% social security contributions	50.0%	50.0%	50.0%
Salary increases	3.3%	4.0%	4.0%
Discount rate	2.90%	3.16%	1.30%

- Retirement age: 64 years old (managers); 62 years old (non-managers);
- 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

	2012	2013	2014
	(Amounts in Euros)		
Social security contribution liabilities	1,158,362	1,708,526	2,160,437
Tax liabilities	62,793	56,062	114,313
Other debts	67,000	52,207	110,052
Deferred revenues from subsidies	127,298	793,72	1,051,528
Total	1,415,453	2,610,515	3,436,329

The other liabilities include the short-term debts to employees, as well as social welfare and tax agencies.

Note 14: Financial Instruments Recognized in the Statement of Financial Position and Related Effect on the Income Statement

	Book value on the statement of financial position	Fair value through profit and loss(3)	Loans and receivables(1)	Debt at amortized cost(2)	Fair Value
2012					
	(Amounts in Euros)				
Financial assets					
Non-current financial assets	384,357	301,358	82,999	—	384,357
Customer accounts receivable and related receivables	92,875	—	92,875	—	92,875
Cash and cash equivalents	38,348,130	38,348,130	—	—	38,348,130
Total financial assets	38,825,362	38,649,488	175,874	—	38,825,362
Financial liabilities					
Conditional advances (non-current portion)	376,651	—	—	376,651	376,651
Conditional advances (current portion)	257,414	—	—	257,414	257,414
Supplier accounts payable and related payables	977,724	—	—	977,724	977,724
Total financial liabilities	1,611,789	—	—	1,611,789	1,611,789
2013					
	(Amounts in Euros)				
Financial assets					
Non-current financial assets	623,829	541,487	82,342	—	623,829
Customer accounts receivable and related receivables	182,900	—	182,900	—	182,900
Cash and cash equivalents	39,402,761	39,402,761	—	—	39,402,761
Total financial assets	40,209,490	39,944,248	265,242	—	40,209,490
Financial liabilities					
Conditional advances (non-current portion)	1,316,533	—	—	1,316,533	1,316,533
Conditional advances (current portion)	126,292	—	—	126,292	126,292
Supplier accounts payable and related payables	4,107,804	—	—	4,107,804	4,107,804
Total financial liabilities	5,550,629	—	—	5,550,629	5,550,629

[Table of Contents](#)

2014	Book value on the statement of financial position	Fair value(3)	Loans and receivables(1)	Debt at amortized cost(2)	Fair Value
	(Amounts in Euros)				
Financial assets					
Long-term financial assets	1,595,861	1,496,036	99,825	—	1,595,861
Customer accounts receivable and related receivables	136,112	—	136,112	—	136,112
Other current financial assets	240,609		240,609		240,609
Cash and cash equivalents	114,583,141	114,583,141	—	—	114,583,141
Total financial assets	116,553,723	116,079,177	476,546	—	116,553,723
Financial liabilities					
Long-term conditional advances	3,854,666	—	—	3,854,666	3,854,666
Long term financial rent debt	33,504			33,504	33,504
Short-term conditional advances	192,000	—	—	192,000	192,000
Short term financial rent debt	20,653			20,653	20,653
Accrued interest	83			83	83
Accounts payable and other liabilities	5,310,958	—	—	5,310,958	5,310,958
Total financial liabilities	9,411,864	—	—	9,411,864	9,411,864

- (1) The fair value of “loans and receivables” corresponds to the value reported in the statement of financial position (value at the transaction date and then tested for impairment on each reporting date).
- (2) The book amount of financial liabilities measured at amortized cost was deemed to be a reasonable estimation of fair value.
- (3) The fair value of financial assets held for trading is determined based on Level 1 fair value measurements and corresponds to the market value of the assets.

Note 15: Operating Income

The operating income is broken down in the following manner:

	2012	2013	2014
	(Amounts in Euros)		
Revenues	174,360	181,800	210,759
Research Tax Credit	2,522,399	3,312,462	4,339,620
Subsidies	79,829	332,051	211,143
Total	4,761,372	3,826,313	4,761,522

The revenues of the Company are composed of the sales of *Diallertest*® products.

Note 16: Operating Expenses

The research and development expenses are broken down as follows:

	December 31		
	2012	2013	2014
	(Amounts in Euros)		
R&D expenses			
Personnel expenses	4,800,518	7,194,722	7,703,057
Sub-contracting, collaboration and consultants	5,229,379	8,212,083	10,703,130
Research supplies	598,216	555,009	937,316
Real estate property rental	259,224	263,438	254,923
Conferences and travel expenses	324,123	465,871	665,420
Allowances for provisions and amortization and depreciation	192,740	290,406	466,172
Others	95,168	385,009	413,424
Total R&D expenses	11,499,368	17,366,538	21,143,442

[Table of Contents](#)

By nature, the breakdown of general and administrative expenses is as follows:

G&A Expenses	December 31		
	2012	2013	2014
	(Amounts in Euros)		
Personnel expenses	3,107,246	4,698,848	5,109,057
Fees	512,709	586,638	1,165,989
Real estate property rental	157,467	111,232	203,899
Insurance policies	56,054	105,018	230,495
Communication and travel expenses	480,999	450,701	645,175
Postal and telecommunications expenses	86,831	65,350	75,913
Administrative supplies and rentals of personal property	65,867	97,131	104,374
Others	131,526	194,832	582,762
Total G&A expenses	4,598,699	6,309,750	8,117,664

Personnel Expenses

The Company employed 56 people as of December 31, 2014, in comparison with 44 as of December 31, 2013.

The personnel expenses are broken down as follows (in Euros):

	2012	2013	2014
Wages and salaries	2,376,638	3,607,544	4,883,410
Social security contributions	2,300,323	3,148,253	3,202,520
Expenses for pension commitments	36,495	89,572	86,781
Share-based payments	3,194,308	5,048,201	4,639,403
Total	7,907,764	11,893,570	12,812,114

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”);

Table of Contents

- 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 3, 2014, the board of Directors issued 75,000 options (“OPTIONS 2014”);
- With the authorization of the General Meeting of Shareholders on June 3, 2014, the board of Directors issued 10,000 BSA (“BSA 2014”);
- With the authorization of the General Meeting of Shareholders on June 3, 2014, the board of Directors issued 186,000 Free shares (“Free shares”);

17.1 BCEX

The BCEX may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to one fourth (1/4) of the BCEX on the first anniversary of the date of grant;
- up to one fourth (1/4) of the BCEX on the second anniversary of the date of grant;
- up to one fourth (1/4) of the BCEX on the third anniversary of the date of grant;
- up to one fourth (1/4) of the BCEX on the fourth anniversary of the date of grant;
- 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 BCEX 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 BCEX

Date of grant (Board of Directors)	01/21/2009	01/21/2009	01/21/2009	01/21/2009
Vesting period (years)	1	2	3	4
Plan expiration date	01/20/2019	01/20/2019	01/20/2019	01/20/2019
Number of BCEX granted	574	574	574	574
Share entitlement per BCEX(1)	15	15	15	15
Exercise price	70	70	70	70
Valuation method used	Black and Scholes			
Grant date share fair value	70	70	70	70
Expected volatility	40%	40%	40%	40%
Average life of BCEX	5.5	6.0	6.5	7.0
Discount rate(2)	2.71%	2.98%	2.98%	3.11%
Expected dividends	0%	0%	0%	0%
Performance conditions	NA	NA	NA	NA
Fair value per BCEX	28.64	30.25	31.46	31.87

[Table of Contents](#)

- (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 BCEX 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 BCE 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 BCEX.

Change in Number of BCEX Outstanding

Number of BCEX	Year ended December 31,		
	2012	2013	2014
Balance at beginning of period	2,296	2,296	2,296
Granted during the period	—	—	—
Forfeited during the period	—	—	—
Exercised during the period	—	—	2,296
Expired during the period	—	—	—
Balance at end of period	2,296	2,296	—

Breakdown of the Closing Balance

Number of BCEX	2012		Year ended December 31,			
	Outstanding	Exercisable	2013		2014	
BCEX with exercise price of €70	2,296	2,296	2,296	2,296	—	—
Total	2,296	2,296	2,296	2,296	—	—

17.2 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 eight (8) 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.

[Table of Contents](#)

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.

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	12/06/2015	12/06/2015	12/06/2015	12/06/2015	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 and Scholes				Black and 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

Table of Contents

- (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	1
Exercise price	8.59	8.59	8.59	8.59	8.1	18.79
Valuation method used	Black and 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(2)	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.

Change in Number of BSA Outstanding

Number of BSA	Year ended December 31,		
	2012	2013	2014
Balance at beginning of period	1,145	120,980	193,980
Granted during the period	119,835	73,000	10,000
Forfeited during the period	—	—	—
Exercised during the period	—	—	7,500
Expired during the period	—	—	—
Balance at end of period	120,980	193,980	196,480

Breakdown of the Closing Balance

Number of BSA	Year ended December 31,					
	2012		2013		2014	
	Outstanding	Exercisable	Outstanding	Exercisable	Outstanding	Exercisable
BSA with exercise price of €65	1,145	1,145	1,145	1,145	1,145	1,145
BSA with exercise price of €5.13	89,835	—	89,835	—	89,835	—
BSA with exercise price of €8.59	30,000	—	30,000	30,000	25,000	25,000
BSA with exercise price of €8.1	—	—	73,000	73,000	70,500	70,500
BSA with exercise price of €18.79	—	—	—	—	10,000	10,000
Total	120,980	1,145	193,980	104,145	196,480	106,645

[Table of Contents](#)

17.3 BSA 2

The BSA may be exercised by the beneficiary on the basis of the following vesting schedule:

- up to 4,822 BSA on the date of grant;
- up to 2,680 BSA on the first anniversary of the date of grant;
- up to 1,072 BSA on the second anniversary of the date of grant;
- up to 1,072 BSA on the third anniversary of the date of grant;
- up to 1,070 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 BSA2 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 BSA2

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 BSA2 granted	4,822	2,680	1,072	1,072	1,070
Share entitlement per BSA2(1)	15	15	15	15	15
Exercise price	65	65	65	65	65
Valuation method used	Black and Scholes				
Grant date share fair value	70	70	70	70	70
Expected volatility	40%	40%	40%	40%	40%
Average life of BSA2	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 BSA2	29.05	30.32	31.89	33.05	33.45

- (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 BSA2 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 BSA2 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 BSA2.

Change in Number of BSA 2 Outstanding

Number of BSA2	2012	Year ended December 31,	
		2013	2014
Balance at beginning of period	10,716	10,716	10,716
Granted during the period	—	—	—
Forfeited during the period	—	—	—
Exercised during the period	—	—	2,667
Expired during the period	—	—	—
Balance at end of period	10,716	10,716	8,049

[Table of Contents](#)

Breakdown of the Closing Balance

Number of BSA2	2012		Year ended December 31,			
	Outstanding	Exercisable	2013		2014	
			Outstanding	Exercisable	Outstanding	Exercisable
BSA2 with exercise price of €65	10,716	10,716	10,716	10,716	8,049	8,049
Total	10,716	10,716	10,716	10,716	8,049	8,049

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 and 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.

[Table of Contents](#)

Change in Number of BCE4 Outstanding

Number of BCE4	2012	Year ended December 31,	
		2013	2014
Balance at beginning of period	5,358	5,358	5,358
Granted during the period	—	—	—
Forfeited during the period	—	—	—
Exercised during the period	—	—	—
Expired during the period	—	—	—
Balance at end of period	5,358	5,358	5,358

Breakdown of the Closing Balance

Number of BCE4	2012		Year ended December 31,			
	Outstanding	Exercisable	2013		2014	
			Outstanding	Exercisable	Outstanding	Exercisable
BCE4 with exercise price of €65	5,358	5,358	5,358	5,358	5,358	5,358
Total	5,358	5,358	5,358	5,358	5,358	5,358

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.

[Table of Contents](#)

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 and Scholes				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 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 and 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.

[Table of Contents](#)

Change in Number of BSA2010 Outstanding

Number of BSA	Year ended December 31,		
	2012	2013	2014
Balance at beginning of period	19,377	11,848	11,848
Granted during the period	—	—	—
Forfeited during the period	7,529	—	—
Exercised during the period	—	—	3,514
Expired during the period	—	—	—
Balance at end of period	11,848	11,848	8,334

Breakdown of the Closing Balance

Number of BSA2010	Year ended December 31,					
	2012		2013		2014	
	Outstanding	Exercisable	Outstanding	Exercisable	Outstanding	Exercisable
BSA2010 with exercise price of €77	11,848	6,845	11,848	9,180	8,334	8,000
Total	11,848	6,845	11,848	9,180	8,334	8,000

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
	1	2	3	4	1	2	3	4
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 and Scholes				Black and 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.

[Table of Contents](#)

Change in Number of BSAX Outstanding

Number of BSAX	Year ended December 31,		
	2012	2013	2014
Balance at beginning of period	2,131	2,131	2,131
Granted during the period	—	—	—
Forfeited during the period	—	—	—
Exercised during the period	—	—	—
Expired during the period	—	—	—
Balance at end of period	2,131	2,131	2,131

Breakdown of the Closing Balance

Number of BSAX	Year ended December 31,					
	2012		2013		2014	
	Outstanding	Exercisable	Outstanding	Exercisable	Outstanding	Exercisable
BSAX with exercise price of €65	2,131	2,131	2,131	2,131	2,131	2,131
Total	2,131	2,131	2,131	2,131	2,131	2,131

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;

Table of Contents

- 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
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				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,		
	2012	2013	2014
Balance at beginning of period	34,039	34,039	34,039
Granted during the period	—	—	—
Forfeited during the period	—	—	—
Exercised during the period	—	—	4,067
Expired during the period	—	—	—
Balance at end of period	34,039	34,039	29,972

Breakdown of the Closing Balance

Number of BCE2010	Year ended December 31,					
	2012		2013		2014	
	Outstanding	Exercisable	Outstanding	Exercisable	Outstanding	Exercisable
BCE2010 with exercise price of €77	34,039	14,510	34,039	23,020	29,972	27,463
Total	34,039	14,510	34,039	23,020	29,972	27,463

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.

[Table of Contents](#)

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.

Details of SO

Date of grant (Board of Directors)	09/18/2013	06/03/2014
Vesting period (years)	4	2
Plan expiration date	09/18/2023	06/03/2024
Number of SO granted	518,000	75,000
Share entitlement per SO(1)	1	1
Exercise price	7.57	19.01
Valuation method used	Black and Scholes	
Grant date share fair value	7.9	19.01
Expected volatility	40%	40%
Average life of SO	7.0	6.0
Discount rate(2)	1.72%	0.89%
Expected dividends	0%	0%
Performance conditions	NA	NA
Fair value per SO	3.57	7.46

(1) Based on French government bonds (GFRN) with a maturity corresponding to the maturity of SO.

Change in Number of SO Outstanding

Number of SO	2012	Year ended December 31,	
		2013	2014
Balance at beginning of period	—	—	518,000
Granted during the period	—	518,000	75,000
Forfeited during the period	—	—	47,000
Exercised during the period	—	—	—
Expired during the period	—	—	—
Balance at end of period	—	518,000	546,000

Breakdown of the Closing Balance

Number of SO	2012		Year ended December 31,			
	Outstanding	Exercisable	2013		2014	
			Outstanding	Exercisable	Outstanding	Exercisable
SO with exercise price of €7.57	—	—	518,000	—	471,000	—
SO with exercise price of €19.01	—	—	—	—	75,000	—
Total	—	—	518,000	—	546,000	—

[Table of Contents](#)

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

Dates of Grant 04/02/2012, 07/25/2012, 11/28/2012, 09/12/2013 and 06/03/2014

The 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%

- (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 100th 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 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.
 - 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.

[Table of Contents](#)

- (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.

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.

Change in Number of Free Shares Outstanding

Number of Free shares	2012	Year ended December 31,	
		2013	2014
Balance at beginning of period	—	839,237	1,340,737
Granted during the period	839,237	501,500	186,000
Forfeited during the period	—	—	83,360
Exercised during the period	—	—	802,017
Expired during the period	—	—	—
Balance at end of period	839,237	1,340,737	641,360

Note 18: Financial Revenue and Expenses

The financial income and expenses are broken down as follows (in Euros):

	2012	2013	2014
Financial revenues	517,540	670,234	727,239
Financial expenses	(25,203)	(24,310)	(103,239)
Total	492,337	645,925	624,000

The financial income is primarily comprised of capital gains on the disposals of investment securities. The foreign exchange losses and the expenses related to the accretion of the OSEO, BpiFrance and COFACE advances are classified in financial expenses.

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.”

[Table of Contents](#)

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% (excluding additional contributions):

	Year Ended December 31,		
	2012	2013	2014
	(in thousands of euros)		
Income (loss) before taxes	(12,912)	(19,306)	(24,012)
Theoretical group tax rate	33.33%	33.33%	33.33%
Nominal tax expense	4,304	6,435	8,003
Increase/decrease in tax expense arising from:			
Permanent differences(1)	1,024	619	3,636
Research tax credit	838	1,096	1,446
Share-based compensation	(1,065)	(1,682)	(1,546)
Non recognition of deferred tax assets related to tax losses and temporary differences	(5,088)	(6,438)	(11,458)
Other differences	(12)	(30)	(81)
Effective tax expense	0	0	0
Effective tax rate	0%	0%	0%

- (1) The significant balance of permanent differences is mainly affected by transaction costs on capital increases occurred in 2013 and 2014. These transaction costs are booked in equity and are subject to a tax deduction.

Deferred Tax Assets and Liabilities

As mentioned in Note 3.15, the Company has not recognized deferred tax assets in the statement of financial position.

Note 20: Commitments

Obligations Under the Terms of the Ordinary Rental Agreements

On April 28, 2011, the Company signed with the company SELECTINVEST a lease for its premises.

On December 1, 2014, an expansion lease was signed between DBV and Nexity (formerly SELECTINVEST1).

The amount of future rents and charges in that capacity was breaks down as follows at December 31, 2014:

(Amounts in Euros)	12/31/2014
2015	386,766
2016	427,565
2017	427,565
2018	427,565
2019	427,565
2020	178,152
Total	2,275,178

The Company signed in July 2014 a lease agreement with EVOSCIENCES to lease laboratory equipment. The future rental payments as at December 31, 2014 are as follows:

- 2015: €20,653;
- 2016: €21,038;
- 2017: €12,466.

Table of Contents

The company has signed various ordinary rental agreements for office equipment and vehicles. The future rental payments as at December 31, 2014 are as follows:

- 2015: €27,338;
- 2016: €22,435;
- 2017: €8,947;
- 2018: €5,219.

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 €384,809.

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.

In 2011, the Company signed a subcontracting agreement with a CRO within the context of launching its Phase II clinical study for the Viaskin Peanut product. This study amounts to €5,390,637. As of December 31, 2014, the amount remaining to pay as part of this contract for years 2015 was €323,123.

The Company signed a subcontracting agreement with the same CRO within the context of launching its follow-up clinical study OLFUS for the Viaskin Peanut product. This study amounts to €6,800,000.

As of December 31, 2014, the amount remaining to pay as part of this contract for years 2015, 2016 and 2017 was €3,402,647.

The Company signed a subcontracting agreement with a second CRO within the context of launching its clinical study for the Viaskin Molik product. This study amounts to €7,050,758.

As of December 31, 2014, the amount remaining to pay as part of this contract for years 2015, 2016, 2017 and 2018 was €5,856,163.

In 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 presented below, which were awarded to the members of the Board of Directors of the Company, were posted to the accounts as expenses during the course of the fiscal years presented (in Euros):

	2012	2013	2014
Members of the Board of Directors	203,450	380,800	433,160
Directors' fees	45,000	40,000	40,000
Share-based payments to members of the Board of Directors	1,211,454	1,612,191	1,117,538
Fees paid to SCP Benhamou Vannrom	164,513	—	—
Total	1,624,417	2,032,991	1,590,698

The methods for valuation of the benefit related to share-based payments are presented in Note 17.

Statement of the debts to related parties as of December 31:

	2012	2013	2014
Exceptional compensation	75,600	109,200	114,660
Directors' fees	67,000	36,500	40,000
Pension obligations	22,845	—	—
Total	165,085	145,700	154,660

Note 22: Earnings Per Share

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 13,604,687 in 2013. The weighted average number of shares was 16,086,247 in 2014.

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 (1,437,684 instruments in 2014 and 2,119,109 instruments in 2013). These instruments are presented in detail in Note 17. Therefore, the diluted earnings per share are identical to the basic earnings per share.

	As of December 31,		
	2012	2013	2014
Net income of the reporting period	(12,912,100)	(19,306,416)	(24,011,880)
Adjusted weighted average number of outstanding shares	12,326,779	13,604,687	16,086,247
Basic / Diluted earnings per share (€/share)	(1.05)	(1.42)	(1.49)

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

The Company could need to strengthen its shareholders' equity or rely on additional financing in order to ensure its development.

Since it was formed, the Company has financed its growth by reinforcing its shareholders' equity through a succession of increases in the share capital, obtaining public assistance in support of innovation, and reimbursements of Research Tax Credit claims, but has never utilized bank loans. Therefore, the Company is not exposed to a liquidity risk resulting from the implementation of any early repayment clauses in loan agreements for such borrowings.

As of this date, the Company believes that it is not exposed to any short-term liquidity risk considering the cash and cash equivalents available as of December 31, 2014, that is, €114,583,141.

Significant research and development efforts and expenditures related to clinical studies have been initiated since the start-up of the Company's business, which has thus far generated negative operating cash flows.

The Company will continue to have significant financing requirements in the future for the development of its technology, the continuation of its clinical development program, and the equipment for its own pharmaceutical laboratory, as well as for the production and marketing of its products in the future. It is possible that the company will find itself unable to self-finance its growth, which would compel it to seek other sources of financing, particularly through new increases in share capital.

The level of the financing requirements of the Company and how they are phased out over time depend on factors that are largely beyond the control of the Company such as:

- higher costs and slower progress than anticipated for its research and development and clinical studies programs;
- the costs of preparing, filing, defending, and maintaining its patents and other intellectual property rights;
- higher costs and longer time periods than anticipated for obtaining the regulatory authorizations for the marketing of its products as well as for gaining access to insurance reimbursement for them, including the time required to prepare the applications to the competent authorities; and
- costs for responding to changes in the Viaskin® technology and for conducting the manufacturing and marketing on some or all of its products;
- new opportunities to develop new products or to acquire technologies, products, or companies.

It is possible that the Company will be unable to obtain additional capital when it needs it, or that such capital may not be available on financial terms that are acceptable to the Company. If the necessary funds are not available, the Company could have to:

- delay, reduce, or eliminate the number or the scope of its pre-clinical and clinical trials;
- grant licenses to its technologies to partners or third parties; or
- conclude new collaboration agreements on terms less favourable to it than those that it could have obtained in a different context.

In addition, to the extent that the Company raises capital by issuing new shares, the investment of its shareholders could be diluted. Furthermore, financing by debt, to the extent that it is available, could also include restrictive conditions for the Company and its shareholders.

The occurrence of one or more of these risks could have a material adverse effect on the Company, its business, its financial position, its earnings, its development, and its prospects.

[Table of Contents](#)

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 3.11).

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 U.S. 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 the fiscal years 2014 and 2013, less than 7% and 10% respectively of the purchases and other external expenses had been made in U.S. dollars, generating a net annual foreign exchange loss of €24,337 and €2,831 respectively for those periods.

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

The second disbursement related to the OSEO Immunavia advance expected in October 2014 was received on January 22, 2015. Given the expenditure declared, the amount received was €864,989.

In 2015, the Company has signed a new lease arrangement in relation to its new premises in Montrouge, France and expects to relocate its current site in Bagneux later in 2015. The maximum cost of leaving the premises in Bagneux is estimated at €415k.

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/ Dr. Pierre-Henri Benhamou

By: Dr. Pierre-Henri Benhamou

Title: Chief Executive Officer (*Principal Executive Officer*)

Date: April 29, 2015

EXHIBIT INDEX

Exhibit	Description	Schedule/ Form	Incorporated by Reference		File Date
			File Number	Exhibit	
1.1	By-laws (<i>statuts</i>) of the registrant (English translation)	Form F-1	333-198870	3.1	09/22/14
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	4.2	10/15/14
4.1	Shareholders' Agreement among the registrant and certain shareholders signatory thereto, dated March 9, 2012 (English translation)	Form F-1	333-198870	4.3	09/22/14
4.2#	Office Lease between the registrant and GENERALI VIE, dated March 3, 2015 (English translation)				
4.3	Commercial Lease between the registrant and SELECTINVEST 1, dated April 28, 2011 (English translation)	Form F-1	333-198870	10.1	09/22/14
4.4	Assignment, Development and Co-Ownership Agreement among the registrant, L'Assistance Publique—Hopitaux de Paris and Université Paris Descartes, date January 7, 2009 (English translation)	Form F-1	333-198870	10.2	09/22/14
4.5†	Form of Indemnification Agreement between the registrant and each of its executive officers and directors	Form F-1/A	333-198870	10.3	10/15/14
4.6†	2013 and 2014 Share Option Plans (English translation)	Form F-1	333-198870	10.4	09/22/14
4.7†	2012, 2013 and 2014 Free Share Plans (English translation)	Form F-1	333-198870	10.5	09/22/14
4.8†	Summary of BSA	Form F-1	333-198870	10.6	09/22/14
4.9†	Summary of BSPCE	Form F-1	333-198870	10.7	09/22/14
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				
#	Filed herewith.				
*	Furnished herewith.				
†	Indicates a management contract or any compensatory plan, contract or arrangement.				

OFFICE LEASE**BETWEEN THE UNDERSIGNED:**

GENERALI VIE, a limited company with a capital 299,197, 104.00 Euros, with its head office situated at PARIS (75009) – 11, Boulevard Haussmann, and registered in the Commercial and Companies Register under number 602 062 481,

Represented by **GENERALI REAL ESTATE S.p.A**, a limited company incorporated under Italian law, with a 780,000.00 € fully paid up capital, whose head office is situated at 1 piazza Duca Degli Abruzzi, 34132 TRIESTE, registered in the Trieste Commercial and Companies register under No.00312080328, identified in the Trieste REA (Economic Administrative Index) under No.98498, acting through its French establishment, situated at 7, boulevard Haussmann – 75009 Paris, registered in the Paris Commercial and Companies Register under No.538 616 988, holder of professional card No. G6000, and of professional card No.°T14667, both issued by the Paris Police Headquarters, and guaranteed as such by the COMPAGNIE EUROPEENNE DE GARANTIES ET CAUTIONS, situated at 128, Rue de la Boétie – 75378 Paris Cedex 08.

A company belonging to the GENERALI group, registered in the Register of insurance groups under number 026

Itself represented by Mr Sébastien PEZET, acting in his capacity as Director to Asset Management, and duly authorised.

ON THE ONE HAND,

AND

DBV TECHNOLOGIES, a company with a capital of 1.886.895,40 €, registered in the Commercial and Companies Register under No. 441 772 522, and which has its head office at Bagneux-92220-80/84, rue des Meuniers-Green Square Bâtiment D,

Itself represented by M. Pierre-Henri BENHAMOU acting in his capacity as Chairman and Chief Executive Officer, and duly authorised for purposes of this lease.

Hereinafter referred to as: the “Lessee”

ON THE OTHER.

Hereinafter jointly referred to as the “Parties”

RECITALS	4
PRELIMINARY DECLARATION	4
PART ONE: GENERAL TERMS AND CONDITIONS	4
ARTICLE 1 - DESCRIPTION	5
ARTICLE 2 - PURPOSE OF THE PREMISES	5
ARTICLE 3 - TERM	5
ARTICLE 4 - RENTS	5
4.1 PAYMENT TERMS	5
4.3 RENT INDEXATION	6
4.4 RENT FOR THE RENEWED LEASE	6
4.5 CONTRACTUAL INTERESTS AND COLLECTION COSTS	8
4.6 PENALTY CLAUSE	8
4.7 ALLOCATION OF PAYMENTS	9
ARTICLE 5 – SECURITY DEPOSIT	9
ARTICLE 6 - CHARGES, TAXES AND FEES, VARIOUS BENEFITS AND CLAIMS BORNE BY THE LESSEE	10
6.1 TAX SYSTEM	10
6.2 CHARGES, TAXES AND FEES	10
6.3 SETTLEMENT AND ALLOCATION OF THE CHARGES, TAXES AND FEES	12
6.4 PAYMENT TERMS	12
ARTICLE 7 - TAKING OF POSSESSION - ENJOYMENT - TERMS FOR EXPLOITATION	13
7.1 ENTRY INTO ENJOYMENT - PROPERTY INSPECTION REPORT	13
7.2 GOVERNMENTAL AUTHORISATIONS - IMPROVEMENTS TO THE PREMISES	13
7.3 GARNISHMENT	14
7.4 OCCUPATION	14
7.5 PARKING SPACES	15
7.6 PRE-EMPTION RIGHT	15
7.7 SUB-LEASING AND DOMICILIATION	15
7.8 ASSIGNMENT OF THE LEASE	15
7.9 LEGAL MODIFICATION	16
ARTICLE 8 – WORKS CARRIED OUT BY THE TENANT	16
8.1 WORKS RELATED TO THE PRIMARY STRUCTURE OR THE COMMON PARTS	16
8.2 OTHER WORKS	17
8.3 END USE OF THE TENANT’S IMPROVEMENT WORKS	18
8.4 EXTERNAL INSTALLATIONS	19
8.5 SIGNS	19
CLAUSE 9 - UPKEEP AND REPAIR WORKS OF THE PREMISES RENTED BY THE TENANT COMPLIANCE WORK - LESSOR’S WORK - VARIOUS INTERVENTIONS	20
9.1 UPKEEP – REPAIRS – COMPLIANCE	20
9.2 WORK CARRIED OUT BY THE LESSOR IN THE PROPERTY OR NEIGHBOURING PROPERTY OR ON PUBLIC ROADS	21
9.3 VISITING THE PREMISES IN THE EVENT OF TERMINATION OF THE LEASE	22
CLAUSE 10 - LIABILITY - WAIVERS	22
10.1 INTERRUPTION/CANCELLATION OF SERVICES	22
10.2 LIABILITIES AND CLAIMS	22
10.3 EXPROPRIATION	23
10.4 DESTRUCTION OF THE RENTED PREMISES	23
CLAUSE 11 - INSURANCE	23
11.1 LESSOR’S INSURANCE	23
11.2 TENANT’S INSURANCE	23
11.3 RECIPROCAL WAIVER OF RECOURSE	24
11.4 DAMAGE	25

ARTICLE 12 - RELEASE OF THE PREMISES	25
12.1 LESSEE'S OBLIGATIONS	25
12.2 PRELIMINARY INSPECTION	25
12.3 – PROPERTY CONDITION REPORT	26
12.4 LEASEHOLD REPAIRS AND RESTORATION WORK	26
ARTICLE 13 - AMENDMENTS – FORBEARANCE	26
ARTICLE 14 - DECLARATION	27
ARTICLE 15 - TERMINATION CLAUSE	27
ARTICLE 16 - ENVIRONMENT AND SAFETY	28
16.1 ASBESTOS	28
16.2 TECHNOLOGICAL RISKS	28
16.3 ENERGY EFFICIENCY ANALYSIS	28
16.4 CLASSIFIED INSTALLATIONS	28
16.5 INSPECTIONS AND WORK BY THE LESSEE	28
16.6 INSPECTIONS CARRIED OUT BY THE LESSOR	29
16.7 IMPLEMENTATION OF ENVIRONMENTAL PROTECTION REGULATIONS	29
ARTICLE 17 - INTERNAL REGULATIONS - PROPERTY OWNER'S ASSOCIATION RULES - HOMEOWNERS ASSOCIATION RULES	30
ARTICLE 18 – FEES AND REGISTRATION	31
ARTICLE 19 – ADDRESS FOR SERVICE	31
PART TWO: SPECIAL CONDITIONS	32
ARTICLE 1 - DESCRIPTION	32
ARTICLE 2 – EFFECTIVE DATE - TERM OF THE LEASE - FIXED TERM	32
ARTICLE 3 – ANNUAL RENT	32
ARTICLE 4 - INDEXATION	33
ARTICLE 5 – SECURITY DEPOSIT	33
ARTICLE 6 - RENT-FREE PERIOD	33
ARTICLE 7 - EARLY HANDOVER OF THE PREMISES	33
ARTICLE 8: SPECIFIC PREPARATORY WORK BY THE LESSEE	34
ARTICLE 9 – FEES, TAXES, AND WORK	34
9.1 FEES	34
9.2 TAXES	34
9.3 WORK	35
ARTICLE 10 - SUBLEASING - REGISTERED ADDRESS	35
10.1. - SUBLEASING	35
10.2. - REGISTERED ADDRESS	36
ARTICLE 11 - SIGN	36

RECITALS

The Lessor is owner of a building located in the Montrouge municipality (92120), on 177-181 boulevard Pierre Brossolette.

The building is 4 storeys high over a first floor and basement that opens onto a interior garden.

PRELIMINARY DECLARATION

This lease has been entered into and accepted according to the charges, clauses and terms and conditions stipulated herein below, as well as in compliance with the legal provisions in force, in particular the status of commercial leases, resulting from the provisions of Articles L 145-1 et seq. and R 145-1 et seq. of the Commercial Code, as well as the provisions of the noncodified decree of 30 September 1953, with which the Lessee undertakes to comply.

The foregoing shall be applicable both to the Lessee and to any assignee or occupant to whom the Lessee's rights shall regularly pass, during the term of this lease as well as during its renewals, if any.

This clause aims to specify the legal, regulatory or contract provisions to which the Parties agree to refer, to the exclusion of any contractual extension of the enjoyment of the status of commercial leases in favour of the Lessee, which must prove that it fulfils the legal or regulatory conditions applicable in particular during renewals.

Under this agreement, the notion of lease covers this lease, its renewals, if any, and/or its extensions, if any, such that, unless as otherwise stipulated, all obligations applicable herein shall apply throughout the term of the lease, its renewals, if any, and/or its extensions, if any.

This deed is divided into two parts that constitute an indivisible whole:

Part One: GENERAL TERMS AND CONDITIONS

Part two: SPECIAL TERMS AND CONDITIONS

it is hereby stated:

- that in the event of contradiction following this lease between the two Parties, the special terms and conditions shall supersede the general terms and conditions,
- that any tolerance, respecting the terms and conditions of this lease and its consequences, whatever the frequency and duration, may never be deemed as an amendment or an elimination of said terms and conditions.

These clauses are crucial for the common intention of the Parties.

* *
*

PART ONE: GENERAL TERMS AND CONDITIONS

ARTICLE 1 - DESCRIPTION

The premises constituting the subject matter hereof, are described under the Special Terms and Conditions. It is specified that any difference between the assessments of the surfaces mentioned under this lease or resulting from the attached plans and the actual dimensions of the leased premises may not justify any reduction or increase in rents, with the Parties stating that they shall refer to the state of the premises as-is and the Lessee in this regard waives any claims on the basis, in particular, of the provisions of Article 1719 of the Civil Code.

The Lessee acknowledges that it has had the opportunity to inspect the premises in their as-is condition, including size and components of the premises with all their outbuildings as provided for under this lease.

The Parties expressly agree that the Premises constitute an indivisible whole.

ARTICLE 2 - PURPOSE OF THE PREMISES

The leased premises are intended to be used exclusively as commercial offices.

The storage of goods, as well as any wholesale or retail-wholesale activity, are strictly forbidden.

The Lessor does not grant the Lessee any exclusive rights, the Lessee being free to grant leases to third parties, even the Lessee's competitors.

ARTICLE 3 - TERM

The effective date and term of this lease are set forth under the Special Terms and Conditions.

ARTICLE 4 - RENTS

This lease has been entered into and accepted in return for annual principal rent, the amount excluding taxes and charges of which is specified under the Special Terms and Conditions.

4.1 PAYMENT TERMS

Rents shall be payable in advance quarterly on the first day of each civil quarter to the Lessor or the Lessor's representative.

For the period between, where applicable, the effective date of the lease, as specified under the Special Terms and Conditions of this lease, and the end of the ongoing quarter, the Lessee, upon receiving an invoice, shall pay the main rent calculated prorata temporis based on the time remaining for the fraction of the quarter. Subsequently, the Lessee shall pay the rent on the first day of each civil quarter.

4.2 BANK TRANSFER

The Lessee shall pay all amounts payable as rents, including the principal rent and associated costs, under this lease by cheque or bank transfer from the Lessee's bank account no later than the first day of the civil quarter into the Lessor's bank account.

In this regard, the Lessor shall give the Lessee a copy of the details of the bank account into which the transfer should be made.

The Lessee shall ensure that enough funds are available on its account to make the transfer possible. The Lessor shall specify the transfer amount to the Lessee at least a fortnight before the each due date.

In the event of a change in Lessor's banking information, the Lessor shall give the Lessee new bank details.

Where, whatever the reason, the payment of the amounts payable at the contractual due date as back rents, charges and associated costs could not be made by bank transfer, the Lessee shall in any case pay by any other method, excluding in cash, the amounts due accordingly, on the first day of each quarter to meet contractual maturities set forth above

4.3 RENT INDEXATION

The rent stipulated hereinabove is linked to changes in the index set forth under the Special Terms and Conditions.

It is specified that this clause is a contractual indexation and does not refer to the three-yearly review provided for under Articles L 145-37 and L 145-38 of the Commercial Code. The Parties are thus justified in expecting the rent to be reviewed in accordance with the public order provisions of said Articles L145-37 and L145-38 of the Commercial Code.

As a result, the rent shall automatically and without any prior formality be increased or reduced each year on the anniversary date of the effective date of the lease to reflect changes in the said index.

For the first rent indexation, the base index shall be the one referred to under the special terms and conditions, and the review index shall be that of the same calendar quarter of the following year.

For subsequent indexations, the base index shall be the previous review index and the review index shall be that of the same calendar quarter of the following year.

It should be noted that the annual rent indexation is an essential and crucial condition of this agreement: where the benchmark index ceases to exist and where the lawmaker fails to automatically replace it with another index, the Parties shall agree to a substitute index and if they do not, the index shall be determined by the President of the Tribunal de Grande Instance (district court) in whose jurisdiction the premises are situated, ruling in emergency proceedings, to whom the matter was referred at the request of the first party to act, with the costs associated with the proceedings shared 50-50 by each of the Parties.

4.4 RENT FOR THE RENEWED LEASE

4.4.1. Principle

As an essential and crucial condition of this lease, it is hereby stipulated that in the event of renewal under the terms and conditions of this lease, the renewal rent shall be set at:

- the market rental value, as defined below,

The price of the renewed lease thus set shall be applicable from the first day when the renewed lease takes effect, even if the price is higher by more than ten per cent (10%) than the last rent paid, by way of derogation from the last paragraph of Article L.145-34 of the Commercial Code.

Unless as otherwise expressly stated, any other clauses and terms and conditions of the Lease shall be maintained and applied under the renewed lease.

4.4.2. Market rental value

The rental value shall in any case be calculated exclusively by comparison with market rents, i.e.,:

- prices freely discussed by the landlord and their tenant for vacant premises, to the exclusion of references to amicable renewals and fixing of rents by the court for signed leases with effective date running during the twelve (12) months prior to the renewal,
- for real property comparable to the premises, i.e., buildings of a similar nature to the building, situated within the same perimeter and having particulars similar to those of the premises (prestige, standard with regard to quality, construction, integrated services, technical equipment, functionality), unless where they are to be corrected if such characteristics fail to meet other reference criteria, subject to such criteria being comparable.

Amounts for the assignment of rights under the lease as well as lease-premium, the amount for work done by the tenants, and the effect, if any, of the progressive nature of rents on the term of leases.

This article is decisive factor in the Parties' willingness, without which the lease would not have been signed, and shall be applicable to any assessor called upon to give an opinion on the rent amount.

4.4.3. Determination of market rental value

The market rental value shall be established, in all cases where it is applicable under the lease, according to the following process, from which the Parties may not depart in any case whatsoever.

- The market rental value, in the absence of agreement between the Parties, shall irrevocably be set by a property valuer chosen from the list of property valuers maintained at the Paris Court of Appeal, it being understood that the valuer must not have worked for one of the Parties within the twelve (12) months prior to their appointment. The valuer's fees and costs shall be borne 50-50 by each of the Parties.
- In the event that the Parties fail to agree on the name of a valuer or where all valuers worked for one of the Parties within the twelve (12) months prior to their appointment, the party that acts first shall refer the matter to the President of the Paris Tribunal de Grande Instance, ruling in emergency proceedings, who shall appoint a valuer.

The valuer shall act within the framework of a common interest mandate, just like the third party charged with calculating the legal price of the sale (article 1592 of the Civil Code).

The valuer shall give its decision within two (2) months of the matter being referred to them. Their decision must irrevocably bind the Parties and may not be appealed.

However, this procedure shall have no impact on the Lessor's option to refuse to renew the lease or on that of the Lessee to terminate their lease as provided for below.

4.4.4. Right of option

It is expressly agreed between the Parties that they shall, no later than within one (1) month of service (by the party that acts first) of the valuer's decision, draw up a new lease under the conditions set forth in said decision, unless the Lessee chooses not to renew the lease or the Lessor refuses to renew it.

a) Where, within a period of one month, the Lessee waives the opportunity to renew the lease, the Lessee must notify the Lessor of such decision by means of an extrajudicial document. In that case, the Lessee may only vacate the premises upon the expiry of a six-month period following the date of notification by the Lessee of its decision to take advantage of this clause, by way of express derogation to the common practice under Article L.145-57 (2) of the Commercial Code.

The Lessee shall continue to be bound during this period by all obligations under the lease, with rents, as a result, being set as provided for under Article 4.4.

a) Where, within a period of one month, the Lessor refuses to renew the lease, the Lessor must notify the Lessee of such decision by means of an extrajudicial document.

4.5 CONTRACTUAL INTERESTS AND COLLECTION COSTS

If any amounts payable, including charges and taxes, are not paid when they fall due, the Lessee shall automatically be required to pay an interest set by contract at the legal interest rate, plus two points, per month from this date.

Moreover, any correspondence sent to the Lessee calling on it to pay a rent or any other amounts remaining outstanding ten days after the due date shall give rise to the collection of a lump sum of fifty euros in administration fees.

Any costs, fees, or emoluments payable to lawyers, bailiffs and auctioneers, in return for any service rendered to collect sums outstanding after the agreed due date, shall be borne by the Lessee as penalties under article 1152 of the Civil Code.

4.6 PENALTY CLAUSE

Also, upon the expiry of a period of eight days following each due date, any amounts payable, plus the late penalties referred to above, shall be automatically increased on a flat-rate basis by 10%, without the need for any formal notice, irrespective of the costs of possible deeds or writs, costs of

proceedings, as well as any interests payable under the law, any damages such as the bringing into play of the defeasance clause, if any.

4.7 ALLOCATION OF PAYMENTS

By way of derogation from Articles 1253 to 1256 of the Civil Code, the allocation of payments of outstanding amounts by the Lessee when they fall due or their contractual maturity date shall be as follows:

- 1 - Cost of collection and proceedings
- 2 - Contractual late payment penalty under Article 4.5 of this lease
- 3 - Amount of the penalty clause under Article 4.6 of this lease
- 4 - Any addition to or adjustment of the security deposit amount
- 5 - Rent, charges or occupation compensation

ARTICLE 5 – SECURITY DEPOSIT

5.1 To guarantee the performance of its obligations under this lease, the Lessee shall pay to the Lessor, upon the signature hereof, an amount representing three (3) months of rent, excluding taxes and charges, as a security deposit.

The non-interest-bearing amount shall be returned to the Lessee at the end of the lease after moving and handing back keys, subject to justification of payment of all taxes and charges, carrying out of repairs for which it is responsible and upon deduction of any amounts payable to the Lessor or for which the Lessor may be held responsible due to an action of the Lessee in any capacity.

Each time the rent is adjusted, both in the event of a review and renewal, the security deposit shall, automatically and without any formality, be reduced or increased in the same proportions such that it at all times shall be equal to three months of the principal rent, excluding taxes and charges.

Since compensation is expressly provided for, the Lessor shall have the right to deduct from said security deposit without any formality, the amounts of rents fallen due but not paid, as well as any other amounts payable for any other reason, in which case the Lessee shall be bound to make up for or replenish the security deposit on first demand in order to maintain the security deposit at all times at the agreed number of rent periods.

Where the lease is terminated in accordance with Article 1184 of the Civil Code or by application of the defeasance clause due to failure to fulfil terms and conditions or for any other reasons attributable to the Lessee, the security deposit shall remain forfeited to the Lessor as up-front damages without prejudice to any other compensation.

5.2 In case of collective procedure by the Lessee and in accordance with Article L.622-7 of the Commercial Code, the Lessor, if it so wishes, may offset the amount of the security deposit against any amounts payable as rents, back rents, occupation compensation, charges, interests or

penalties, on account of they are all related. The Parties have immediately decided that the security deposit shall as a priority be set off against rents prior to the court ruling initiating the collective procedure.

The Lessee or the assignee shall fully replenish the security deposit by giving the Lessor the corresponding amount.

Furthermore, if the administrator or liquidator were to terminate the lease by waiving the option granted under Article L. 622.13 of the Commercial Code, the failure to fulfil terms and conditions shall result in damages payable to the Lessor, which damages the Parties have agreed to set at a flat-rate basis and finally at three months of rents including taxes.

ARTICLE 6 - CHARGES, TAXES AND FEES, VARIOUS BENEFITS AND CLAIMS BORNE BY THE LESSEE

This lease has been entered into at a rent net of charges, taxes and fees for the Lessor in accordance with the following terms and conditions.

6.1 TAX SYSTEM

The rent, as well as charges and taxes collected by the Lessor shall be subject to the tax system referred to under the special terms and conditions. The Lessor reserves the possibility of making the rent liable to another tax system, a possibility that the Lessee has accepted, under conditions that exclude any change to the pre-tax amount of the applicable rent.

6.2 CHARGES, TAXES AND FEES

6.2.1 Taxes, charges and fees

The Lessee shall reimburse the Lessor its share of taxes and fees, even those generally payable by the Lessor, including domestic refuse removal charges, street-clearing charge, property tax surcharge, annual tax on office space, business premises, storage premises and parking areas situated at Ile-de-France, all thoroughfare occupation taxes, including management fees related to local taxation, as well as taxes, charges and fees linked to the use of the leased premises or the building or to a service used directly or indirectly by the Lessee, as well as other existing taxes and charges or those that may be created subsequently and likely to be payable by the Lessor as owner of the leased premises.

Similarly, the Lessee shall pay any contributions or taxes resulting from its activities in the leased premises, as well as power, telephone or other bills, by signing any agreements required for the purpose, such that the Lessor may in no case whatsoever be troubled in this regard.

6.2.2 Charges, miscellaneous services and other receivables

Apart from the rent, the Tenant will be obliged to pay to or reimburse the Landlord for the share relating to the leased premises, of the taxes, duties and charges, as well as the charges and services, namely all operating, repair and maintenance expenses, energy performance and/or environmental improvements to the building, or replacements to the leased premises, the building or their equipment, even if these expenses result from fair wear and tear, from force majeure or from a hidden defect, but with the exception of charges, taxes, duties, fees and works which cannot be

charged to the Tenant by virtue of Article R 145-35 of the Commercial Code in its draft in effect on the date of signature of the present lease. The Tenant will also bear the cost of all expenses incurred to bring the leased premises, building or their equipment into compliance with the regulations which are currently applicable or which may be so in the future, but only within the limits set by Article R 145-35 of the Commercial Code.

In accordance with Article R 145-35 of the Commercial Code in its draft in effect on the date of signature of the present lease, the following remain the responsibility of the Landlord:

- the expenses relating to major repairs mentioned in Article 606 of the Civil Code as well as, where applicable, the fees related to the completion of these works
- the expenses relating to works which are intended to repair fair wear and tear or to ensure compliance with the regulations for the leased premises or the building in which they are located, where the said works are covered by the major repairs mentioned in Article 606 of the Civil Code

In application of the said article, the above-mentioned expenses which relate to decorative works for which the amount exceeds the cost for identical replacements will remain the responsibility of the Landlord.

As a consequence and in application of the principles stipulated above, the Tenant will reimburse to the Landlord its share of the following categories of charges, taxes, duties and fees:

- cleaning, maintenance and repair costs for the common areas or shared use parts
- rendering costs
- the costs for the elimination of shared waste
- the costs of maintenance, repairs and renewal of the equipment and tooling necessary for the management and operation of the building, installation/modifications to the metering systems (water, electricity and more generally all fluids) (but only within the limits set by Article R 145-35 of the Commercial Code)
- the costs of maintenance, repairs, compliance, obligatory and periodic conformity inspections under the terms of the regulations applicable to ICPEs (Installations Classified for the Protection of the Environment), replacements of items of equipment in the building and of all installations necessary for its proper operation such as, in particular, the lifts, service lifts, cleaning units, electrical generators, power switches, sprinters, transformers, electrical panels, boilers, etc.
- the costs of audit, measurement and monitoring of the environmental performances of the building
- the expenses incurred for monitoring and optimising the emissions of greenhouse gases or the energy consumption of the building and/or or improving its environmental performances and bringing it into compliance with the requirements originating in the heating regulations (but only within the limits set by Article R 145-35 of the Commercial Code)
- the costs of acquisition and renewal of the floral decorations or minor furniture, as well as the maintenance costs for the gardens where applicable
- the remuneration, with social security and related charges included, of the staff allocated to the building and in particular to security, surveillance, cleaning, safety or maintenance, as well as the costs incurred by the use of external contractors in these areas
- the fees for technical assistance
- the costs of lighting, heating and cooling, such as cooling or air conditioning if they exist, the costs of maintenance or replacement of the corresponding equipment, ventilation and generally any consumption of fluids whatsoever
- the costs of maintenance, repair and renovation of the roadworks, including the delivery and common or private parking areas

-
- the remuneration of the administrators responsible for the technical management of the building, fixed at 2.50% of the annual rent excluding taxes, the fees of the management syndicate, the costs of management and functioning of the ASL/AFUL where applicable
 - the premiums for the insurance policies contracted for the entirety of the building or the these premises in accordance with the terms set out for this purpose in Article 11 of the general conditions of the present lease
 - all the taxes, charges and fees reimbursable by the Tenant to the Landlord in accordance with the conditions set out in Article 6.2.1 above

The above inventory of the categories of charges, taxes, fees and dues related to the present lease, representing, as of today's date, an exhaustive list. The Landlord will however, at any time during the course of the lease, be able to inform the Tenant of new charges, taxes, fees and dues related to the lease, which will be reimbursable in their entirety in the amount of its share, in accordance with the provisions of Article L 145-40-2 of the Commercial Code by the Tenant in accordance with the conditions set out in Article 6.4 below.

6.3 SETTLEMENT AND ALLOCATION OF THE CHARGES, TAXES AND FEES

Payment will be made prorata to the floor area rented or percentage of the leased premises as these are shown where applicable in the co-ownership regulations and the descriptive report of the division if the building is placed under the co-ownership regime and as a results from the terms provided for this purpose in the specific conditions, it being specified that the floor area rented or percentage of the leased premises are established based on the floor area used, with the Tenant not bearing the charges, taxes, fees and use relating to the vacant floor areas in the building.

The Landlord reserves the option, which is expressly accepted by the Tenant, to make any necessary modifications to the allocation of the charges (percentages allocated to the leased premises), in the event of modifications of the conditions of enjoyment and operation of other premises in the building, or changes in the services supplied based on modifications made to the improvements fitted in the said building, with the Landlord being obliged in this case to so inform the Tenant.

6.4 PAYMENT TERMS

The payment of the charges will be made at the same time as the rent and in accordance with the same conditions, in accordance with a provisional statement established quarterly for the year during which the leased took effect, in accordance with the specific conditions - the amount of the provisional payment is likely to be readjusted each year by the Landlord, taking into consideration the amount of the charges paid in the previous year.

The Landlord will be entitled to include in the above-mentioned provision the share of the taxes and charges stipulated above or to make one-off calls for them.

The payment of the fees of the administrators responsible for the technical management of the building and the premiums relating to the insurance policies will be made at the same time as the rent and, where the insurance policies are concerned, once per annum.

The final adjustment to the expenses account will be carried out on an annual basis and in accordance with the summary statement of expenses actually incurred, as prepared by the Landlord or its representative in respect of each financial year.

In the event of the departure of the Tenant, after the return of the keys, the balancing payment will be made based on a statement which will be sent to it. In the event of a debit situation of the Tenant, it will be payable on receipt of the statement. If it is in credit, it will be reimbursed at the same time that the statement is sent.

ARTICLE 7 - TAKING OF POSSESSION - ENJOYMENT - TERMS FOR EXPLOITATION

7.1 ENTRY INTO ENJOYMENT - PROPERTY INSPECTION REPORT

As an exception to the provisions of Article 1720 of the Civil Code, the Tenant will take the leased premises in the condition in which they are found, without being able to require from the Landlord any works of any kind whatsoever, or any restoration, including any intervention is required with a view to bringing the leased premises into conformity with their contractual intended use.

A property inspection report will be prepared in the presence of both parties by the Parties on the effective date of the present lease. In the event of an assignment of the leasing right, or the disposal or transfer on a free-of-charge basis of the business goodwill, a new property inspection report will be established between the Landlord and the new tenant. At the request of either of the Parties, the latter may be prepared by a bailiff mandated for this purpose by the Landlord, with the cost shared equally between the Parties.

In the event that the Landlord has invited the Tenant to this property inspection and the report, for any reason, is not prepared and in particular if the Tenant should abstain from participating, the premises will be considered to have been least in a very good state of maintenance and repair.

7.2 GOVERNMENTAL AUTHORISATIONS - IMPROVEMENTS TO THE PREMISES

At the time of taking possession of the premises, the Tenant will be personally responsible, at its exclusive expense, for all governmental authorisations required for the exercise of its activities; the same will be true for any interventions required in the premises to bring these into compliance with any applicable legal or regulatory prescriptions, either as a result of its contractual intended use, or the characteristics of the premises or their environmental performances, without being able to exercise any right of recourse against the Landlord.

In the event that the execution of improvement works should be necessary - for any reason whatsoever - the Tenant will bear the cost of all the technical and financial constraints which arise therefrom - regardless of the nature or cost - in compliance with the regulations applicable at the date on which the works are carried out, and this without any right of recourse against the Landlord, complying in this regard with all the obligations arising from Article 8 of the General Conditions of the present lease.

The Tenant shall be obliged to inform the Landlord of the governmental authorisations obtained and to provide it with a copy.

Lastly, the Tenant hereby renounces any right of recourse in this respect against the Landlord for any reason whatsoever.

7.3 GARNISHMENT

The Tenant will be obliged to keep the leased premises continuously garnished with furniture and equipment in sufficient quantity and value to cover the proper execution of the conditions of the present agreement at any time.

7.4 OCCUPATION

The Tenant will be obliged to personally occupy the leased premises. It shall be prohibited from lending them or granting the enjoyment thereof, even temporarily or free-of-charge, and from hosting a third party there.

It will submit to all measures for the order and cleanliness of the building in which the leased premises are located and undertakes in particular:

- not to encumber, in any way whatsoever, even temporarily, with objects of any kind whatsoever, the parts of the building which are shared with the other occupants
- not to use any machine or equipment of which the noise, odour or vibrations and emanations would trouble the peaceful enjoyment of the other tenants or neighbours
- not to deposit in the leased premises any merchandise or any installation of a kind to give rise to the dangers of explosions or bad odours
- to supervise the behaviour of the employees and any person for which the Tenant may be responsible in any respect whatsoever, in order to avoid problems with the neighbours
- not to overload the floors

7.5 PARKING SPACES

The Tenant will only use the parking spaces to park the passenger vehicles of its employees or visitors, to the exclusion of any activity such as, in particular, repairs, oil changes or cleaning.

It will not stock there any equipment or object of any kind, in particular tyres or cans of petrol or oil

It will comply with the operational and safety rules for the car parks as shown in the regulations governing the buildings and their subsequent modifications.

It will collect and return, on first request from the Landlord, the magnetic cards or, more generally, the means of access which may have been supplied to it in order to allow for their replacement or periodic delegation, or at the end of the lease.

7.6 PRE-EMPTION RIGHT

By express derogation from Article L. 145-46-1 of the Commercial Code, the Tenant renounces any pre-emption right in the event of the transfer of the leased premises or the building.

7.7 SUB-LEASING AND DOMICILIATION

Sub-letting, total or partial, in the leased premises is prohibited.

Any domiciliation in the leased premises is prohibited.

7.8 ASSIGNMENT OF THE LEASE

The Tenant will not be entitled to assign or make a contribution of its right to the present lease, unless it is to the buyer of its business goodwill and this subject to informing the Landlord in advance.

In the event of a merger or de-merger of companies, or in the event of a universal transfer of assets of a company completed in accordance with the terms set out in Article 1844-5 of the Civil Code or in the event of the contribution of a part of the assets by a company carried out in accordance with the conditions set out in Articles L. 236-6 L 236-22 and L 236-24 of the Commercial Code, the company originating from the merger, the company designated by the de-merger contract or, failing this, the companies originating from the de-merger or the company which is the beneficiary of the universal transfer of assets or the company which is the beneficiary of the contribution shall be substituted for that in favour of which the lease was granted, in all the rights and obligations arising from this lease.

The assignor, as well as its successors will remain the joint guarantors and respondents for the payment of the rents and incidental amounts, as well as for the execution of the clauses of the present lease, and this without there being any need to inform them of the first unpaid amount within a deadline of one month, by express derogation from Article L. 145-16-1 of the Commercial Code.

By express derogation from Article L. 145-16-2 of the Commercial Code, this joint guarantee will last throughout the term of the lease, plus three years, and this regardless of the period during which the business was operated by one of them.

This joint guarantee will be due both by any assignor in respect of the assignees, and reciprocally by any assignee in respect of any assignor and this without the Landlord being obliged to carry out any formality or denunciation particularly in the event that extended payment terms should be granted on an amicable or judicial basis to the principal debtor. The guarantee will remain due in the event of the termination of the lease for any reason whatsoever, during the period of effective occupation of the premises, until their complete vacation and the return of the keys.

The assignor and the assignee will take personal responsibility for everything concerning the reimbursement between themselves of the guarantee deposit, it being specified that in no event will the assignment be a reason for the reimbursement by the Landlord of the said guarantee deposit.

The Landlord, except in the event of a merger or de-merger or of a universal transfer of assets or partial contribution of assets carried out in accordance with the terms set out in Articles L. 236-6-1, L. 236-22 and L. 236-24 of the Commercial Code, will be called to add its support to the deed of assignment or contribution 15 days prior to the effective date of signature of the latter, by registered letter with acknowledgement of receipt, to which will be attached the draft definitive deed of assignment or contribution. A certified copy or an original registered copy of the deed of assignment will have to be delivered within a deadline of 15 days, at no cost, to the Landlord, to be used by it as an enforceable title.

In no event will the Tenant be able to complete the said assignment or the said contribution if it is not up-to-date in advance with the payment of all the rents, charges and incidental expenses due to the Landlord.

7.9 LEGAL MODIFICATION

The capacity of the Parties present being a determining condition of the lease, the Tenant undertakes to notify, without delay, to the Landlord, by registered letter with acknowledgement of receipt, any information liable to impact the financial capacity of the Tenant (pledge, collective procedure, etc.).

It also undertakes to inform the Landlord, in the forms set out in Article 1690 of the Civil Code, of any merger, partial contribution of assets, de-merger or universal transfer of its assets, by providing to it the supporting documents for the modifications made to the registration of the company or companies concerned at the Register of Trade.

ARTICLE 8 – WORKS CARRIED OUT BY THE TENANT

8.1 WORKS RELATED TO THE PRIMARY STRUCTURE OR THE COMMON PARTS

The Tenant will not be entitled to drill any holes in the walls or floors, carry out any demolition or construction, or make any intervention on the facade of the building or works affecting the common areas, the technical installations of the building, its environmental performances or its external

appearance, without the prior written consent of the Landlord and, where applicable, of the Syndicates of Co-owners and/or the Free Syndicate Association ("ASL"), to which the descriptive cost estimates and the plans will have to be submitted in advance.

In addition, these works, where appropriate, will have to be carried out in full compliance with the co-ownership regulations, the regulations of the Free Syndicate Association and with the Internal Regulations of the building and all changes thereto.

Lastly, these works may only be carried out subject to the following conditions:

- prior issue of the governmental authorisations required, depending on the nature of the planned works
- subscription by the Tenant of the insurance policies required to cover its third party liability in respect of the execution of any building site as well - depending on the nature of the works carried out - as in respect of the two-year and ten-year guarantees and this in conformity with the legislation in effect
- informing the Landlord's architects by the Tenant or its project manager of the progress on the building site, with dispatch of all execution plans allowing for the compliance of the works carried out with those which were previously authorised to be checked

The fees of the Landlord's architect shall be borne entirely by the Tenant,

- compliance with the legislation relating to employment law, health and safety and Establishments Open to the Public, to roadways, cleanliness, the police, the Employment Inspectorate and the protection of the environment

The Tenant will be obliged to undertake its works, to continue them with diligence and to complete them within the agreed deadlines and to complete them in compliance with the environmental annex if such exists.

The Landlord's authorisation will in no event incur its liability, nor attenuate that of the Tenant, both between the Parties and with regard to third parties.

The Tenant undertakes to bear all the consequences of its works, which may be prejudicial to the primary construction and to the solidity of the building, and to compensate the Landlord and any third party for any losses, of any kind whatsoever, which may be caused by the execution of the said works.

8.2 OTHER WORKS

The improvement and internal decorative works on the premises will be carried out by the Tenant at its expense, after obtaining the agreement of the Landlord or its representative or from the co-ownership syndicate and the governmental authorisations which may be required, and in accordance with the conditions indicated in the descriptive estimate which it will be obliged to have prepared and to provide to the Landlord.

Indeed, prior to the execution of the works, the Tenant will be obliged to submit its file of improvements to the Landlord or to its representative in order (i) that it can verify its compliance with the Co-ownership Regulations and/or the Regulations of the Free Syndicate Association, if the

building is subject to such resumes, as well as to the Internal Regulations of the building, (ii) and that it can give or not give its authorisation.

The Tenant will be obliged to undertake its works, to continue them with diligence and to complete them within the agreed deadlines and to complete them in compliance with the environmental annex if such exists.

Any authorisation from the Landlord for the completion of the works covered in the present article does not imply any commitment of responsibility on its part; consequently, the Tenant undertakes not to take proceedings against the Landlord, and this even if the works or the contractors have been approved by the latter.

It is hereby specified that the authorisation given, where applicable, by the Landlord will be an authorisation in principle and that in no event will the Landlord guarantee the feasibility of the planned works or the various consequences which may result therefrom.

All controls, verifications and works to which the leased premises, the improvements, installations and equipment which they contain may be subject, as a result of applicable or future regulations, will be entirely at the expense of the Tenant, which renounces any right of recourse against the Landlord, including four deteriorations and hindrances to enjoyment which are likely to result therefrom.

The Tenant will therefore alone assume the complete responsibility which may result from the execution of these works and will be obliged to cover or have covered all the risks by insurance policies subscribed in accordance with the provisions set out in the present lease.

In the event of completion of works without the agreement of the Landlord, the latter will be entitled to require that the leased premises are restored, at the expense of the Tenant, to their original state, without prejudice to the application of the sanctions incurred under the terms of the present lease or the legislation in effect.

8.3 END USE OF THE TENANT'S IMPROVEMENT WORKS

8.3.1. All works, decorations, improvements, installations, building works and highest increases whatsoever (including fixed, mobile or movable partitions) and, where applicable, the works imposed by the applicable regulations, carried out by the Tenant, either on its entry into the premises or during the course of the lease, will become, by means of accession, at the end of each of the successive leases or prior to that date if the lease is terminated early, the property of the Landlord, without compensation.

The Landlord may nevertheless require, on the departure of the Tenant, the restoration of the premises, in whole or in part, into their original state, at the expense of the Tenant, even for works authorised by the Landlord and even for those which may have been the subject of accession to the latter at the time of a previous lease renewal.

The original state of the premises means that mentioned in the property inspection report prepared at the time of entry into enjoyment of the Tenant, and as shown, where applicable, on the plan appended thereto. In the event of the assignment or free-of-charge transfer of the leasing rights, this property inspection report corresponds to that prepared with the initial tenant which concluded the lease and not to that prepared between the Landlord and the assignee or the beneficiary of the leasing right at the time of its entry into the premises.

The restoration works necessary to remedy any damage resulting from the removals will be the responsibility of the Tenant.

8.3.2. In any event, the Tenant will bear the costs related to the improvements, additions, building works and height increases made by it, until the end of the enjoyment of the premises and this even when these have been transferred to the Landlord.

The Tenant will thus be obliged to bear the costs resulting from defects, malfunctions and conformity defects related to the legal standards which may affect the improvements, additions, building works and height increases carried out by it.

The Tenant will also be obliged to bear the costs of maintenance and, where applicable, bringing into compliance of the improvements, additions, building works and height increases carried out by it, until the end of the enjoyment of the premises. It will check that these are, at the time of their completion and at any time subsequently, in compliance with the requirements of the heating regulations.

The Tenant undertakes to guarantee the Landlord against any claim by a third party or neighbour in respect of the improvements, additions, building works or height increases carried out by it.

8.4 EXTERNAL INSTALLATIONS

The Tenant will not be entitled to carry out any installation of awnings, verandas, windbreaks, external blinds or any surface-mounted objects on the facade of the building without having previously obtained the express written consent of the Landlord, as well as the governmental authorisations required for this purpose and, where applicable, the agreement of the Co-ownership Syndicate of the building and/or the Free Syndicate Association.

In the event that the required authorisations should be granted to it, it will be obliged to maintain the installations or improvements made in a very good state of maintenance and to monitor their solidity in order to avoid any accident; it commits, at the time of its departure, to removing the said installations and returning the premises in their original state, unless agreed otherwise between the Parties.

In addition, the Tenant will be obliged to pay all the taxes and charges arising from these installations.

8.5 SIGNS

The Tenant will only be entitled to install an external sign (illuminated or not) with the written agreement of the Landlord or its representative, and if necessary of the Management Syndicate, the General Meeting of the Co-owners or the Free Syndicate Association, to which must be sent in advance the price quotations and plans allowing for determination of the exact details of the installation of the planned change.

In the event of a refusal of the authorisation by the management syndicate, the General Meeting of co-owners or the Free Syndicate Association, the Tenant hereby renounces any rights in this respect against the Landlord on any grounds whatsoever.

The Tenant will be obliged to take personal responsibility for obtaining any governmental authorisations required, and also for the payment of any charges due for this purpose.

It will ensure that the sign is always solidly attached and will remain solely responsible for any accidents which this installation may occasion.

Any modification to the installation of the existing signage, of any kind whatsoever, will have to be the prior subject of a request for authorisation from the Landlord in accordance with the terms stipulated previously.

The Tenant undertakes to insure that, at the time of its departure, the sign is removed and the premises are restored to their original condition.

ARTICLE 9 - UPKEEP AND REPAIR WORKS OF THE PREMISES RENTED BY THE TENANT - COMPLIANCE WORK - LESSOR'S WORK – VARIOUS INTERVENTIONS

9.1 UPKEEP – REPAIRS – COMPLIANCE

For the purposes of paragraphs a) to d) of clause 9.1, the parties agree that, pursuant to Article R 145-35 of the French Commercial Code in the wording in force on the date of signature of this lease, the following fall on the Lessor:

- the expenses for the major repairs listed in Article 606 of the Civil Code and, where appropriate, the fees for the execution of those works,
- the expenses for works to fix the poor state of, or bring into line with regulations, the rented premises or the building in which they are located, once those works have addressed the major repairs mentioned in Article 606 of the French Civil Code.

In accordance with that article, the aforementioned expenses for upgrading work for which the amount exceeds the cost of an identical replacement shall fall to the Tenant.

a/ The Tenant shall keep the premises and their fittings in very good condition and shall carry out maintenance and repairs of any kind, including for damage resulting from usage, dilapidation, a hidden defect and force majeure.

The Tenant must, in particular, at its own expense and under its own responsibility, keep in a very good working condition, safe and compliant with the standards necessary, throughout the duration of the lease, its renovation or refurbishment, the upkeep and repair of all closing devices, doors, glazing, general locks, floors, pipes, taps and all specific facilities and fittings, such as electronic or telephonic fittings, computer cabling, meters, outlets and drains, and bathroom facilities. This list is only indicative and not exhaustive. To that end, the Tenant shall, at its expense take out all upkeep and maintenance contracts, with a view to ensuring that the fittings work and are maintained, and undertakes to supply the Lessor with a copy of those contracts upon the latter's request.

The Tenant must also maintain, repair or replace at its own expense and under its own responsibility, any glazing which covers some parts of the rented premises (but only within the limits set under Article 145-35 of the French Commercial Code) and shall have no legal remedy against the Lessor for damage caused by water leaks from that glazing.

The Tenant shall also refurbish as often as necessary and at least every nine years any painting, wall-coverings and flooring.

In general, the Tenant shall, at its own expense and under its own responsibility, repair or replace anything, when they become necessary and for any reason whatsoever.

The Tenant shall take out at its own expense all maintenance contracts for the appliances or equipment installed in the rented premises and shall ensure that all security and prevention fittings work and are maintained, so that the Lessor may not be pursued or bothered by anyone on that subject.

b/ The Tenant shall be responsible for any repairs which would normally fall to the Lessor but which are needed because either the Tenant has failed to make any necessary repairs under its responsibility or the Tenant, its staff or visitors have caused damage in either the rented premises or other parts of the building.

The Tenant must inform the Lessor without delay of any repairs likely to fall to the latter.

The Lessor shall only be responsible for expenses arising from the major repairs mentioned in article 606 of the French Civil Code and, where necessary, the fees for the execution of those works, except for expenses arising from upgrading work for which the amount exceeds the cost of identical replacement, pursuant to article R145-35 of the French Commercial Code.

c/ Whether during the lease or during possible renovation works, the Tenant must scrupulously comply, at its own expense, with all legal or regulatory provisions in force or which become applying after this lease is signed, with particular regard to refuse, hygiene, health, safety, police, inspection of the work and environmental protection, including thermal regulations. Furthermore, the Tenant shall carry out, at its own expense and under its own responsibility but only within the limits set out in Article R 145-35 of the French Commercial Code, works to ensure that the premises and its facilities comply with all legal and regulatory provisions so that the Lessor is never bothered or pursued by anyone on that subject.

d/ In order to check the condition of the rented premises, the Lessor reserves the right to visit them subject to a notice period of 2 working days. However, the Lessor may visit the premises without providing any notice in the event of an emergency.

Any checks, inspections and works to which the rented premises or the appliances, fittings and facilities within them may be subject, under applicable or future regulations, shall fall fully to the Tenant, who waives the right to any remedy against the Lessor, including for damage and disturbances likely to arise caused by them.

9.2 WORK CARRIED OUT BY THE LESSOR IN THE PROPERTY OR NEIGHBOURING PROPERTY OR ON PUBLIC ROADS

The Tenant shall endure, without compensation or rent reduction, irrespective of their length, even if it exceeds twenty-one (21) days, by derogation from Article 1724 of the French Civil Code, major repairs and any works which must be carried out in the premises or on the property, particularly work to improve environmental performance, on its own initiative, the initiative of the Lessor, neighbours or third parties, even if they do not benefit the Lessor, and any nuisance caused

by those works. The Tenant shall endure works carried out on neighbouring buildings or public roads in the same conditions, and the Lessor may not be held liable for any reason whatsoever.

Furthermore, by derogation from Article 1723 of the French Civil Code, the Tenant must also endure, without compensation or rent reduction and without remedy against the Lessor, any modification to the premises or communal areas and items in the property, that the latter reserves the right to carry out.

The Tenant must in any case leave free access to the water and gas pipes, electrical wiring, heating, air-conditioning and ventilation shafts or other channel, and must, at its own expense and without delay, move or dispose of all appliances, furniture, materials, signs, etc. which must be removed to carry out any works by the Lessor, including in particular when cleaning or carrying out work to improve the building's environmental performances.

9.3 VISITING THE PREMISES IN THE EVENT OF TERMINATION OF THE LEASE

Once notice for the termination of the lease has been given and for at least the last six months of this lease, or in the event that the rented premises are put up for sale, the Tenant must allow potential tenants accompanied by an employee of the Lessor to visit the premises, on any working day, subject to a notice period of 2 working days. Furthermore, the Tenant must leave notices, including banners, affixed to the windows or balconies.

ARTICLE 10 - LIABILITY - WAIVERS

10.1 INTERRUPTION/CANCELLATION OF SERVICES

The Tenant may not claim any compensation or reduction in rent, or hold liable the Tenant, its representatives and their respective insurers in the event of a temporary interruption, an irregularity or a temporary cancellation to the following services: water distribution, electricity, telephone, any automatic system and IT system depending on the property, air conditioning, ventilation or any other related to the property.

10.2 LIABILITIES AND CLAIMS

The Tenant expressly waives the right:

- to request compensation or a rent reduction in the event of damp or a flood caused by water leaks or pipe breakages, for any reason whatsoever, to hold liable the Tenant, its representatives and their respective insurers, for disturbances or damage caused by neighbours or third parties, in any way, particularly in the event of theft or misappropriation, of which the Tenant, its staff, suppliers customers or visitors may be victim in the rented premises or in the property, and the Lessor is not obliged to provide any surveillance.
- to hold the Lessor liable, in the event of physical or non-physical damage, for compensation for loss of use or operating loss, as a result of the total or temporary stop to its activity for any reason whatsoever.

The Tenant shall be personally responsible for:

-
- the repair of any physical or non-physical damage, acting directly against the perpetrators without remedy against the Lessor.
 - any complaints from neighbours or third parties, particularly because of noise, smells, heat or generally any damaged caused by its activity, and the Lessor shall not be bothered in any event of that type.

10.3 EXPROPRIATION

In the event of expropriation in the public interest, no claims may be made against the Lessor; it shall fall to the Tenant to assert any rights arising from this agreement and from the activities carried out in the rented premises on the expropriating party.

10.4 DESTRUCTION OF THE RENTED PREMISES

In the event that, following an accident of any kind, irrespective of its origins, the rented premises are left fully unusable or destroyed, this lease shall be terminated ipso jure and without compensation.

If the rented premises come to be partially destroyed or unusable, the Lessor, alone and depending the extent of the damage, may either terminate this lease ipso jure or agree a rent reduction for the length of the partial loss of use. It is specified that, in the latter case, and on the condition that the Lessor rebuilds the property within a maximum deadline of two years, this lease shall continue to concern all the rented premises and the rent reduction shall be calculated according to the size of the area destroyed. This shall be calculated by the Lessor or its representative. In the event that the Tenant does not agree with the calculation, the Parties agree that they shall bring the matter before the competent court and, while they wait for its decision, they shall provisionally accept the calculation by the Lessor or its representative.

In the aforementioned situations, the Lessor shall, nevertheless, retain its possible rights against the Tenant if the destruction can be partially or fully attributed to the latter.

Accordingly, the Tenant may only, under express agreement, claim compensation awarded by the insurance company or companies for the damages caused to it, without prejudice to the ensuing consequences with regard to this lease according to the terms stipulated below.

ARTICLE 11 - INSURANCE

11.1 LESSOR'S INSURANCE

The Lessor has taken out insurance policies to cover the building and/or rented premises against the risk of fire, explosions, electrical damage, storms, water damage, riots, attacks, acts of terrorism and sabotage, and loss of earnings. It has also taken out civil liability insurance in its capacity as a property owner.

The Parties agree that the potentially applicable excesses shall be borne by the Tenant.

11.2 TENANT'S INSURANCE

The Tenant must take out insurance, for the entire duration of the lease, for a sufficient amount, to cover its fixtures, fittings, equipment, appliances and amenities, and the improvements, extensions, structures and storeys it has added, even if they are immovable by nature, as well as its operating loss, with a reputedly solvable company against the risk of fire, explosions, electrical damage, storms, water damage, riots, attacks, acts of terrorism and sabotage, and claims by neighbours and third parties. The Tenant must also have the rented premises insured against glass breakage.

In the event of an accident, if the Tenant considers the sums that it will have received under its 'Operating Loss' policy, no remedy may be pursued against the Lessor.

The Tenant undertakes to take out a civil liability insurance policy to cover for damages caused to third parties resulting from its operations or the improvements, extensions, structures and storeys it has added on the premises. Physical injuries must be covered to a minimum of €3,000,000 per accident and physical and consequential non-physical damage to a minimum of €760,000 per accident. This minimum may be increased at the request of the Lessor.

The Tenant must send the Lessor a copy certified as conforming with the original of its policies or, failing that, a cover note or statement, in which, where relevant, the improvements, extensions, structures and storeys it has added are mentioned. The document must be issued by its insurer and, the first time, before it has been implemented.

It should also be able to prove the validity of its insurance and the payment of its premiums at any moment.

If the Tenant fails to take out the aforementioned insurance policies or if the Lessor considers those policies not to cover large enough sums, the latter may take out insurance for the risks itself, and the Tenant shall undertake to reimburse the Lessor for the relevant premiums upon request.

Furthermore, the Lessor undertakes to inform the Lessor of any change in its operating conditions which the insurance company could consider an increased risk. If the Tenant's activity or the change in operating conditions results in a higher premium, either for the Lessor or for the neighbours or other tenants, the Tenant shall reimburse the interested parties for the amount of the higher premium.

Likewise, if the improvements, extensions, structures and storeys added by the Tenant results in a higher premium for the Lessor, the Tenant undertakes to bear the cost.

By express agreement, under this lease, compensation due to the Tenant in the event of an accident, amounting to the compensation that the Lessor owes to the Owner, may be delegated and transferred to the Lessor.

The Tenant also undertakes to comply with any request made by the Lessor's insurers aimed at modifying the technical fittings for the prevention and security of the rented premises.

Furthermore, in the event that the Tenant carries out work in the rented premises in the conditions set out in Clause 8, that party must take out the necessary insurance for that purpose and third-party liability cover in particular for the works, as well as a Ten-Year Guarantee and guarantees for Proper Operation, Consequential Damage and Damage to Existing Property in compliance with the legislation in force.

11.3 RECIPROCAL WAIVER OF RECOURSE

The Lessee waives the right to any recourse that it may exercise against the Lessor, its principals or representatives, or its insurers. It agrees to obtain the same waiver from its insurers, any of its occupants and their insurers, and to indemnify the Lessor for the direct or indirect consequences of any claim or legal action that its occupants, employees and/or insurers may frame or bring against the Lessor, including all costs and expenses that the Lessor may incur when exercising its rights.

Reciprocally, the Lessor, its principles and representatives waive the right to any recourse against the Lessee and against its insurers. They agree to obtain the same waiver from their insurers.

11.4 DAMAGE

The Lessee shall inform the Lessor or its representative, within 48 hours, of any repair that becomes necessary during the lease, as well as any damage or deterioration that occurs at the leased premises, regardless of its significance, even if no apparent damage has occurred, subject to being held personally liable and therefore being required to compensate the Lessor for any direct or consequential damage incurred by the Lessor for late filing or failure to file a notice of claim with the insurers.

It must declare any damage to its own insurance company, regardless of the occurrence date and its apparent seriousness.

ARTICLE 12 - RELEASE OF THE PREMISES

12.1 LESSEE'S OBLIGATIONS

Regardless of the reason for the Lessee's relinquishment of the leased premises, it must return the property in a very good state of maintenance and repair and in full compliance (but only within the limits set forth in Article R 145-35 of the Commercial Code), according to its obligations under this lease.

The same shall apply to any modifications or improvements described in Article 8 of the lease, unless the Lessor prefers that the premises be returned in their original condition as stated in Article 8.3.

12.2 PRELIMINARY INSPECTION

No later than two (2) months prior to the Lessee's departure date, a joint inspection of the premises shall be carried out in the presence of any technician or manager appointed by both Parties. If no date is determined by mutual agreement, the Lessor shall inform the Lessee of the dates and times it will appear to inspect the premises.

At this time, any upkeep or maintenance agreements entered into by the Lessee, as well as any supporting documentation concerning maintenance or replacement work performed during the past two years, shall be provided to the Lessor or its representatives.

At the end of this inspection, the Lessor shall send a statement of repairs to be performed by the Lessee, as well as a list of work it requires to restore the property to its original condition and

replacements following any removals, without prejudice to any reservations which may be made when the property condition report is prepared upon the return of the premises.

The Lessee agrees to return the premises after full completion of the repairs, work and replacements defined above, from the moment it is required to do so under the terms of this lease.

The Lessee shall pay an occupancy charge corresponding to the amount of the latest contractual rent increased by 50% during the time required to perform the work, if such work continues beyond the effective date of the notice.

12.3 – PROPERTY CONDITION REPORT

A check-out property condition report will be jointly prepared by the parties, in two original copies, signed and initialled by each of them, on the date the premises are returned.

At the request of either party, this report may be prepared by a bailiff, appointed by the Lessor for this purpose at the Lessee's expense. In such case, the report will be sent by the bailiff, by registered letter with acknowledgement of receipt, to the Lessee at the address it provided during return of the premises.

If, for any reason, the Lessee does not appear on the date it was called by the Lessor, the property condition report prepared by the Lessor shall be deemed to have been jointly prepared.

12.4 LEASEHOLD REPAIRS AND RESTORATION WORK

After retaking possession of the premises and taking into account the reservations set forth in the report prepared at that time, the Lessor shall prepare a descriptive report and a cost estimate for the work it deems necessary, and shall notify the Lessee thereof by registered letter with acknowledgement of receipt no later than fifteen (15) days after the date the premises were returned.

Within fifteen (15) days from receipt of this notice, the Lessee must inform the Lessor if it intends to dispute the nature or cost of the work required by the Lessor. If the Lessee does not respond upon expiry of this time period, the estimate(s) as well as the restoration work planned by the Lessor will be deemed accepted and the Lessor will have the right to have such work performed by the companies of its choice, for which the Lessee will bear the cost, including any charges and fees for work performed by any contractor.

If the Lessee disagrees, each party concerned shall take any action it deems necessary to reserve its rights, without prejudice to any consequences which may result from an extended inability to use the premises for this reason.

Moreover, if, whether due to this dispute or due to the performance of work under the procedures set forth above, the premises are unavailable for use beyond the established release date (effective date of notice or of termination), daily compensation equal to the contractual rent payable upon expiry of the lease increased by 30%, as well as pro rata expenses and taxes arising from this lease, shall be owed by the Lessee.

ARTICLE 13 - AMENDMENTS – FORBEARANCE

This lease can be amended only by a written document. Accordingly, in no case can an amendment be inferred from mere forbearance by the Lessor, whether in frequency or duration, and the Lessor remains free to require strict application of the provisions and stipulations which have not been the subject of an express written amendment.

ARTICLE 14 - DECLARATION

The Lessee attests that it has the necessary capacity to enter into this lease and declares:

- that it is not insolvent or involved in compulsory liquidation, a reorganisation order, a stay of proceedings or any other process arising under applicable provisions of the Commercial Code in this event;
- that it is not subject to proceedings likely to result in confiscation of its property,
- that it does not lack the legal capacity to exercise a commercial occupation.

ARTICLE 15 - TERMINATION CLAUSE

In the event of non-payment of a single rent payment or occupancy charge (including charges and services), any supplemental rent or summary of charges, or in the case of failure to perform any condition of this lease, this lease may be immediately terminated in the Lessor's discretion, one month after an order to pay or a formal warning to comply with the terms of the lease remains without effect.

In such case, the Lessor shall retain the security deposit and rent paid in advance, without prejudice to any damages.

All costs of the notice of default and the proceedings will be borne by the Lessee.

From the date the Lessor's rights under the termination clause are deemed acquired, the occupancy charge owed until release of the property will equal the effective contractual rent increased by 50%, in addition to expenses and taxes.

The lease shall terminate without the need for any legal formalities by the Lessor, without prejudice to any costs or damages. No subsequent payments shall cancel the effects of this provision.

Eviction from the leased premises may be obtained by a simple order issued by the President of the Tribunal de Grande Instance (Regional Court), on an expedited basis, finding that the termination clause is applicable.

The Lessor will regain the right to freely dispose of the premises by the mere fact of the Lessee's eviction, issued by provisional order, and subsequent offers shall not cancel the effects of this provision, without prejudice to its right to receive payment of all rent accrued or payable in advance until the acquisition date of this termination clause, the occupancy charge due thereafter under the procedures set forth above as well as the repair costs borne by the Lessee, subject to all other amounts owed, rights and causes of action.

ARTICLE 16 - ENVIRONMENT AND SAFETY

16.1 ASBESTOS

The Lessor declares that all investigations required by law or regulation have been conducted, and it shall make all supporting documentation available to the Lessee, especially in the event its availability is required in the scope of the improvements to be performed on the leased premises.

16.2 TECHNOLOGICAL RISKS

In accordance with the provisions of Articles L 125-5, R 125-23 to R 125-27 of the Environment Code regarding disclosure of the statement of natural, mining and technological risks to the new tenant, the Lessor provided such disclosure or risks to the Lessee upon signing of this lease, who acknowledges such, including the required information concerning the building where the leased premises are located.

The Lessor further declares that, to its knowledge, the premises have not incurred any damage giving rise to payment of insurance compensation covering natural disasters (Article L. 125-2 of the Insurance Code) or technological risks (Article L. 128-2 of the Insurance Code).

16.3 ENERGY EFFICIENCY ANALYSIS

In addition, the energy efficiency analysis as described under Article L. 134-1 of the Building and Housing Code is also attached to this lease. The Lessee acknowledges that it has reviewed this document.

16.4 CLASSIFIED INSTALLATIONS

If the building includes one or more installations classified for environmental protection subject to declaration or authorisation/registration, the Lessee must comply with all recommendations and injunctions of any kind, including upgrades to the installation(s) to comply with regulations, such that the Lessor is at no time involved in this issue. In addition to maintenance work and upgrades, it must perform at its expense all inspections and verifications required by law or regulation and, with regard to common equipment, shall bear the cost thereof.

In the event that the Lessor authorises the Lessee to install one or more pieces of equipment falling under legislation on classified installations for purposes of its business, in addition to the paragraph above, it must also carry out the necessary administrative formalities to declare itself an operator of these classified installations, and to solely bear the cost of compliance measures and work which the administration requires by law. The Lessee shall indemnify and hold the Lessor harmless against all liability which may result from the presence of such installations on the Premises, their use and their removal.

16.5 INSPECTIONS AND WORK BY THE LESSEE

16.5.1. The Lessee shall cause environmental and safety inspections to be performed at its expense, by entities approved by the *Commission Plénière des Assurances de Biens et de Responsabilité*, in particular concerning the search for hazardous materials and compliance with current regulations on its improvements and any work it may perform. The Lessee will provide the Lessor with a copy of inspection reports prepared by these organisations within one month from their receipt, specifically including any requirements, recommendations or reservations expressed as well as any measures to be taken by the Lessee to satisfy them, including work performed. Within one month following completion of such measures, the Lessee shall provide the Lessor with a report prepared by these same organisations, validating the measures and work carried out, it being specified that such work and/or measures must be carried out under the conditions set forth in Article 8 of the lease, and within three months following the submission of reports by the organisation, unless a shorter period is imposed by such organisations. If the Lessee fails to perform the above mentioned measures and work within this time period, the Lessor shall have the right to have such measures and work carried out by any company of its choice, at the Lessee's expense.

16.5.2. When carrying out the work, either at the start of the lease or during possession, in addition to Article 8 of the lease, the Lessee agrees not to use any materials that may pose a danger to the safety of the occupants of the premises and/or the building.

If the materials used by the Lessee are subsequently prohibited by a new provision, it shall immediately take personal responsibility for any consequences resulting therefrom - research, surveys, removal, compensation or otherwise - without any recourse against the Lessor, even if such work has since become the property of the Lessor.

The Lessee shall take all necessary steps to avoid any risk of pollution and perform all necessary remediation work at its expense.

16.6 INSPECTIONS CARRIED OUT BY THE LESSOR

During the term of the lease, the Lessee shall provide the Lessor with free access to the premises to have organisations of its choice perform any audits or inspections, specifically concerning environmental and/or safety matters, periodic inspections of the building's installations and equipment, and any work and measures arising therefrom. The cost of these audits and inspections, as well as the cost of work and/or measures that must be performed subsequent to such audits and inspections, shall be borne by the Lessee, but only within the limits set forth in Article R. 145-35 of the Commercial Code. In response to its specific, occasional requests and for its information only, the Lessor shall provide the Lessee with a copy of the inspection reports. Note that all inspections, verifications and work to which the building, improvements, installations and equipment within may be subject under current or future regulations, particularly those concerning the safety of persons, are the Lessee's full responsibility, but only within the limits set forth in Article R 145-35 of the Commercial Code, which waives any recourse against the Lessor in this regard, specifically for the deterioration, disturbance of quiet enjoyment and financial consequences that may result therefrom.

16.7 IMPLEMENTATION OF ENVIRONMENTAL PROTECTION REGULATIONS

The Parties agree to work together in order to improve the environmental performance of the building and in order to meet the objectives and recommendations of the Grenelle I Act (law no. 2009-967 dated August 3, 2009 on the timetable for the implementation of the Grenelle Round

Table on the Environment) and the Grenelle II Act (law no. 2010-788 dated July 12, 2010 on national commitment for the environment) and any additional laws.

For this purpose:

- Each party agrees to communicate to the other all of the data in their possession relating to energy consumption, water consumption, and greenhouse gas emissions for the common areas of the building and/or private areas of the premises. They shall communicate, if any, the carbon footprint of the building or the carbon footprint of the activity conducted in the premises.
- Each Party agrees to incorporate an environmental aspect in its decision making processes relating to improvements and/or equipment of the building or premises, or relating to how they are managed in order to opt for the most effective solutions, whenever it is reasonably possible so as to never jeopardize the certifications and/or's ecolabels obtained.

If the Parties do not reach an agreement on the choice of works and installations to carry out to improve the environmental performance of the building, the Lessor shall be free to decide which work or installations shall be carried out that he deems pertinent to improving the building's performance or required to meet any changes in legislation and/or the Grenelle Round Table on the Environment.

For all work and/or installations to improve the building's environmental performance that do not fall under ordinary maintenance or replacement, the Lessee shall be required to:

- Grant access to the premises in order to enable them to be carried out.
- Bear the full costs, fees, and insurance included but only within the limits stipulated by Article R 145-35 of the French Commercial Code.
- And, after completion of the work and/or installations, comply with the specifications of use.

Finally, all Parties shall abide by the terms of the Environmental Appendix if it exists.

ARTICLE 17 - INTERNAL REGULATIONS - PROPERTY OWNER'S ASSOCIATION RULES - HOMEOWNERS ASSOCIATION RULES

If they exist, the Lessee acknowledges having read the building's internal regulations, the property owners' association rules, and/or the homeowner's association rules. He further acknowledges that a copy of each document was given to him.

These documents have contractual value in the same way as this lease.

Consequently, the Lessee agrees to comply with all of their provisions as well as any amendments thereto.

In addition, the Lessee must comply with the conditions and obligations of all property owners' association rules, internal regulations, specifications, or any document governing the building the premises is part of, should they exist.

He must also comply with any rules the building is subject to.

ARTICLE 18 – FEES AND REGISTRATION

The fees and expenses of this document as well as all registration fees, duties, or taxes of any nature whatsoever which may be required to be paid when this lease and additional documents are concluded shall be at the Lessee's expense who hereby agrees.

All fees and expenses payable if any amendments are needed during the lease or its renewal shall also be at the Lessee's expense who hereby agrees.

ARTICLE 19 – ADDRESS FOR SERVICE

For the purposes hereof, the Parties choose their address for service as follows:

- The Lessor at his headquarters indicated above.
- The Lessee at the leased premises.

* *
*

PART TWO: SPECIAL CONDITIONS

ARTICLE 1 - DESCRIPTION

The Lessor hereby leases to the Lessee, who accepts, the entire building located at 177-181, avenue Pierre Brossolette, Montrouge (92120), France, comprised of:

- **Premises for use as offices with a leasable area of approximately 3,712.90 m² from the ground floor to the 4th floor.**
- **Premises for business use with a leasable area of approximately 756.70 m² on the ground floor.**
- **90 parking spaces on the 1st underground floor of the building, 6 of which are motorcycle parking spaces.**
- **21 outside parking spaces at the rear of the building.**
- **3 outside parking spaces in front of the building.**

as identified on the plans annexed hereto.

Before signing this lease, the Lessor had a report made of the surfaces areas by the licensed surveyor firm BLOY and a copy of the report relating to the premises under this lease has been attached.

It is hereby specified that on the date this lease is signed, the building is not subject to property association rules or homeowner association rules and, because it is occupied by one tenant, it has no internal regulations.

ARTICLE 2 – EFFECTIVE DATE - TERM OF THE LEASE - FIXED TERM

This lease is granted for a period of nine (9) full consecutive years starting on August 1, 2015 and ending July 31, 2024 in the manner prescribed for this purpose by the terms of this lease.

By way of derogation from Article L 145-4 of the French Commercial Code, the Lessee expressly waives the right to give notice of termination for each of the first two three-year periods and irrevocably commits to a fixed term of 9 years.

ARTICLE 3 – ANNUAL RENT

1,482,532.00 EUROS (one million four hundred eighty-two thousand five hundred thirty-two euros) excluding fees and taxes which is broken down as follows:

- Rent for offices and business: 1,318,532.00 euros
- Rent for underground parking spaces: 134,000.00 euros
- Rent for underground motorcycle parking spaces: 6,000.00 euros
- Rent for outside parking spaces: 24,000.00 euros

ARTICLE 4 - INDEXATION

Index: the rent index of tertiary activities (ILAT) published quarterly by the INSEE

Date of first indexation August 1, 2016

Base Index: 1st quarter of 2015

Adjustment Index: 1st quarter of 2016

ARTICLE 5 – SECURITY DEPOSIT

The amount of the security deposit is equal to three (3) months of the annual rent excluding taxes, or 370,633.00 euros (three hundred seventy thousand six hundred thirty-three euros) which the Lessee commits to paying when the lease is signed.

ARTICLE 6 - RENT-FREE PERIOD

As an exception and on a purely commercial basis, a rent-free period for the main rent is agreed upon for a period of **20.5 (twenty and a half)** months after the lease takes effect.

The first rent payment will be payable pro rata temporis on April 15, 2017.

During this period, the Lessee shall pay the charges, taxes, duties, fees, services, and other receivables in the manner prescribed for this purpose in the General and Special Conditions of this lease.

The rent-free period shall have no impact on the annual adjustment of the rent pursuant to the indexation clause in the manner prescribed for this purpose by Article 4 of the General Conditions, nor shall it impact the enforceability and calculation of the charges, taxes, duties, fees, services, and other receivables that may be based on the rent.

The Lessee acknowledges that this exemption will have no impact on establishing the new rent amount if this lease is renewed.

ARTICLE 7 - EARLY HANDOVER OF THE PREMISES

On an exceptional and personal basis, the Lessor authorizes the Lessee to access the premises in advance as of April 15, 2015, solely for the purposes of preparing and conducting preparatory work as well as installing his equipment and furniture in the leased premises (without his staff occupying them or starting operations).

This early handover shall give rise to an inventory and condition of the property being drawn up in the presence of both Parties. This inventory shall constitute the inventory referred to under Article 7.1 of the General Conditions of the lease. The early handover of the premises shall be conducted pursuant to the costs and conditions of this lease. However, it is hereby specified that:

- the effective date of the term of the lease as stipulated in Article 2 of the Special Conditions shall occur automatically and without formality on August 1, 2015.

-
- that the Lessee will not pay rent during the early handover period, the rent shall only become payable automatically and without formality on August 1, 2015 without prejudice to the rent-free period agreed upon in Article 6.
 - Moreover, all expenses, taxes, insurance premiums, and other additional fees related to the rent and services stipulated in this lease shall be fully payable by the Lessee during this early handover period.

We also remind you that the Lessee must take out the insurance policies stipulated in Article 11.2 of the General Conditions to cover the early handover period as well as all of the necessary insurance policies for carrying out the work referred to in Article 8 of the General Conditions of the lease, and must show proof by submitting an insurance certificate to the Lessor when the initial inventory and condition of the property is being drawn up that proves the policies have been taken out and are in force from the date the early handover of the premises took place.

The Lessee shall remain liable to comply with all of the provisions contained in Article 8 of the General Conditions.

The early handover of the premises shall entail, as of its effective date, the taking of possession of the premises by the Lessee and the transfer of its custody and risks to the Lessee for the term of the lease.

ARTICLE 8: SPECIFIC PREPARATORY WORK BY THE LESSEE

The Lessor hereby authorizes the Lessee to install an animal house for its activities of pharmaceutical research on the ground floor of the building with a maximum surface area of 100 m².

This authorization is given, subject to the Lessee ensuring and obtaining the administrative, hygiene, and health permits required for this facility so that the Lessor may by no means be held liable.

If, for any reason whatsoever, the Lessee is not able to obtain the necessary permits and/or is not able to carry out his project, he waives holding the Lessor liable.

ARTICLE 9 – FEES, TAXES, AND WORK

9.1 FEES

Merely for informational purposes, the provision for rental costs is provisionally determined for 2015 at a rate of 40,000.00 euros per quarter.

9.2 TAXES

The aforementioned rent is subject to VAT at the legal rate in effect at the time of each rent payment or any other tax which may replace it.

9.3 WORK

9.3.1 Attached to this lease is a summary of the work done by the Lessor over the previous three years and its cost.

Also attached to this lease is an estimate of the work that the Lessor intends to carry out in the building over the next three years with an estimated budget. As needed, it is hereby stipulated that this estimate, which will be updated at least every three years by the Lessor, was only prepared on a purely provisional basis and is therefore likely to be amended at any time by the Lessor which the Lessee is fully aware of. As a result, the Lessee may not claim any reduction of rent or compensation whatsoever, nor may ask for reimbursement of expenses in the event that all or part of the proposed work is not done, as in cases where the Lessor carries out work that was not initially planned.

9.3.2 In addition to the general conditions of this lease, it is stipulated that the Lessor shall bear the cost of replacing all of the doors and windows and modules making up the facades of the leased property.

ARTICLE 10 - SUBLEASING - REGISTERED ADDRESS

10.1. - Subleasing

By way of derogation from Article 7.5 of the General Conditions of this Lease, the Lessee is authorized to partially sublease the premises to:

- An outside company for up to a maximum of 30% of the leased areas.
- One or more of the Lessee's subsidiary companies, with a maximum of 3, according to the criteria defined by Article L 233-1 of the French Commercial Code or any other text that might subsequently replace it, up to a limit of 49% of the leased areas,

without the subleased areas exceeding 50% of the leased areas.

The sublease must be entered into in accordance with the law under the same terms and conditions as the master lease for a period not exceeding the master lease.

The Lessee must justify to the Lessor, by informing him of his intention to sublease under the terms of Article L 145-31 of the French Commercial Code, that the sublessee and the beneficiary meet the conditions required for this purpose.

Unless otherwise agreed by the Lessor, the existing legal relationship between the sublessee and the Lessee must be maintained throughout the term of any sublease and the Lessee must justify it to the Lessor at his first request.

If the Lessor fails to participate in the document, an original copy of the contract shall be given or sent to him within a period of fifteen days from the date it was signed.

In the event of subleasing, the Lessee shall remain solely responsible vis-à-vis the Lessor for paying the rent, expenses, and related fees, as well as full enforcement of the conditions and obligations of the lease.

The Lessee shall be responsible for paying for the preparatory renovations and repair work to the leased premises after any sublease.

The leased premises constitute an indivisible whole both materially and according to the joint intent of the Parties. The provisions of this indivisibility clause must be reproduced in any sublease document which should therefore stipulate that by express agreement between the parties, the currently rented premises constitute an indivisible whole materially and according to the joint intent of the Parties.

If the master lease is not renewed or in the event of the departure of the primary tenant no matter what the cause (leave, amicable or court-ordered termination, availing oneself to the termination clause), resulting in the termination of the lease, the sublease agreement shall be terminated ipso jure. The sublessee shall not be entitled to derive any rights with regard to the Lessor from the status of the commercial leases, and in particular from the direct right to renew the lease derived from Article L 145-32 of the French Commercial Code.

10.2. - Registered Address

As an exception and by derogation from the General Conditions of the lease, the Lessee is authorized to register up to a maximum of 5 of his subsidiaries pursuant to the criteria stipulated by Article L 233-1 of the French Commercial Code at the leased premises or any other text which may subsequently replace it under the following main conditions:

- a) The Lessee agrees to ensure that the companies headquartered there strictly enforce the terms and provisions of this lease which the Lessee shall remain fully liable for vis-à-vis the Lessor.
- b) When the Lessee leaves, the premises shall be returned unoccupied and the Lessee expressly agrees to make the companies registered at the premises make the same commitment.

Please be reminded that this derogation is non-transferable and is exclusively granted under the main and decisive condition that the premises constitute an indivisible whole according to the joint intent of the Parties otherwise it would not have been granted.

Furthermore, no plaque or mailbox shall be installed displaying the names of the registered individuals.

ARTICLE 11 - SIGN

The Lessor hereby authorizes the Lessee to install a sign starting on the early handover date of the premises which is April 15, 2015.

This authorization is granted to the Lessee free of charge and no rent or royalty shall be required from the Lessee by the Lessor for this purpose.

However, it is stipulated that this authorization shall only be granted to the Lessee and validated after the technical file is submitted to the Lessor which shows a photomontage and the proper administrative and technical authorizations, all validated by a technical control bureau for mounting, wind resistance, and studying structures.

The Lessee agrees to obtain the required administrative and technical authorizations before installing a sign and shall pay for all of the taxes and/or charges related to the sign throughout the term of the lease.

In the event that the Lessee does not obtain the authorizations referred above or is not able to install the sign no matter what the cause may be, he agrees from this point forward not to take recourse against the Lessor for this purpose.

The Lessee agrees that he shall remove the sign that he made at his own expense and liability and return the premises in their original condition upon his departure.

Drafted in Paris
On March 3, 2015
In two copies

THE LESSOR

THE LESSEE

Appendices:

Appendix 1: Plans/surveys of the surfaces
Appendix 2: Lessee's bank account information
Appendix 3: Lessor's bank account information
Appendix 4: KBIS extract (company registration certificate) of the Lessee's company
Appendix 5: Environmental Appendix
Appendix 6: ERNMT (Natural, Technological or Environmental Risk Report)
Appendix 7: Energy performance analysis
Appendix 8: Lessee's Proof of Insurance
Appendix 9: Summary statement of the work done in the building and estimates of the projected work

Subsidiaries

	<u>Name of Subsidiary</u>		<u>State or Other Jurisdiction of Incorporation</u>
DBV Technologies Inc.		Delaware	

**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, Pierre-Henri Benhamou, 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)) 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) 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
 - (c) 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 29, 2015

/s/ Pierre-Henri Benhamou

Name: Pierre-Henri Benhamou

Title: Chief Executive Officer (*Principal Executive Officer*)

**Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, 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)) 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) 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
 - (c) 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 29, 2015

/s/ David Schilansky

Name: David Schilansky

Title: Chief Operating Officer (*Principal Financial Officer*)

**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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Pierre-Henri Benhamou, 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; 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 29, 2015

/s/ Pierre-Henri Benhamou

Name: Pierre-Henri Benhamou

Title: Chief Executive Officer (*Principal Executive Officer*)

**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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Schilansky, Chief Operating 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; 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 29, 2015

/s/ David Schilansky

Name: David Schilansky

Title: Chief Operating Officer (*Principal Financial Officer*)

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-199513) of DBV Technologies S.A. (the “Company”) of our report dated April 29, 2015, relating to the consolidated financial statements of the Company, appearing in the Annual Report on Form 20-F of the Company for the year ended December 31, 2014.

/s/ Deloitte & Associés
Represented by Fabien Brovedani
Neuilly-sur-Seine, France
April 29, 2015