



# 2013 HALF YEAR FINANCIAL REPORT





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## I – FIRST HALF 2013 CONDENSED FINANCIAL STATEMENTS

### CONDENSED BALANCE SHEET

(Amount in euros)

	Note	<u>30/06/2013</u>	<u>31/12/2012</u>
		€	€
<b>ASSETS</b>			
<b>Fixed Assets</b>			
Long-term intangible assets		40,996	14,012
Property, plant, and equipment		1,609,065	988,283
Long-term financial assets		607,897	384,357
<b>Total Fixed Assets</b>		<b><u>2,183,555</u></b>	<b><u>1,386,652</u></b>
<b>Current assets</b>			
Inventories and work in progress		12,215	29,673
Customer accounts receivable and related receivables		13,796	92,875
Other current assets		4,303,415	3,117,487
Cash and cash equivalents		32,266,844	38,348,130
<b>Total Current Assets</b>		<b><u>36,596,270</u></b>	<b><u>41,588,165</u></b>
<b>TOTAL ASSETS</b>		<b><u>38,779,825</u></b>	<b><u>42,974,817</u></b>
<b>PASSIF</b>			
<b>Shareholders' equity</b>			
Corporate Share Capital	6	1,340,815	1,340,815
Premiums related to the Share Capital		54,620,910	54,612,601
Reserves		(14,589,656)	(3,768,281)
Income or Loss		(7,906,957)	(13,012,000)
<b>Total Shareholders' Capital</b>		<b><u>33,465,112</u></b>	<b><u>39,173,135</u></b>
<b>Long-term Liabilities</b>			
Conditional advances	7	1,411,036	376,651
Long-term Provisions		311,065	254,941
<b>Total Long-term Liabilities</b>		<b><u>1,722,101</u></b>	<b><u>631,592</u></b>
<b>Current Liabilities</b>			
Conditional advances	7	128,000	257,414
Bank overdrafts		-	519,499
Supplier Accounts Payable and Related Payables	8	1,518,560	977,724
Other current liabilities	8	1,946,051	1,415,453
<b>Total Current Liabilities</b>		<b><u>3,592,611</u></b>	<b><u>3,170,090</u></b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>		<b><u>38,779,825</u></b>	<b><u>42,974,817</u></b>



**CONDENSED PROFIT AND LOSS STATEMENT**  
(Amount in euros)

	Note	As at 30 June	
		2013	2012
		€	€
<b>TOTAL REVENUES</b>			
Sales	9	72,735	71,704
Other income	9	1,263,284	1,244,382
<b>TOTAL REVENUES</b>		<b>1,336,019</b>	<b>1,316,086</b>
<b>Operating expenses</b>			
Cost of goods sold		52,546	54,987
Research & Development	10/11	6,824,121	5,094,902
General & Administrative	10/11	2,716,033	1,796,010
<b>Total Expenses</b>		<b>9,592,700</b>	<b>6,945,899</b>
<b>Operating Profit (Loss)</b>		<b>(8,256,681)</b>	<b>(5,629,813)</b>
Financial revenues	12	359,447	212,021
Financial expenses	12	(9,722)	(15,137)
<b>Financial profit (loss)</b>		<b>349,725</b>	<b>196,884</b>
Corporate tax		-	-
<b>Net Profit (Loss)</b>		<b>(7,906,957)</b>	<b>(5,432,929)</b>
<b>Basic earnings per share (EUR/share)</b>		<b>(0,59)</b>	<b>(0,48)</b>

	As at 30 June	
	2013	2012
	€	€
<b>Net Profit (Loss)</b>	<b>(7,906,957)</b>	<b>(5,432,929)</b>
Other items in the total profit (loss):	-	-
<b>Total profit (loss) for the fiscal year</b>	<b>(7,906,957)</b>	<b>(5,432,929)</b>



**CONDENSED CASH FLOW STATEMENT**  
(Amounts in euros)

<b>Note</b>	<b>30/06/2013</b>	<b>30/06/2012</b>
	<b>€</b>	<b>€</b>
<b>Cash flows from operating activities</b>		
Results for the reporting period	(7,906,957)	(5,432,929)
<b>Reconciliation of the net income (or loss) and of the cash used for the operational activities:</b>		
Amortization and depreciation	182,966	112,333
Retirement pension obligations	56,676	39,457
Other items excluded from the cash	2,050,334	1,095,108
Expenses calculated related to the payments in shares		
<b>Operating cash flows before change in working capital</b>	<b>(5,616,980)</b>	<b>(4,186,031)</b>
Inventories and work in progress	17,458	9,381
Customer accounts receivable	79,079	(41,750)
Other receivables	(1,373,191)	(802,400)
Supplier accounts payable	540,836	(815,723)
Other current liabilities	717,861	(441,323)
<b>Change in working capital requirement</b>	<b>(17,957)</b>	<b>(2,091,815)</b>
<b>Net cash flow from operating activities</b>	<b>(5,634,937)</b>	<b>(6,277,846)</b>
<b>Cash flows from investment activities</b>		
Acquisitions of property, plant, and equipment	(788,809)	(108,810)
Acquisitions of long-term intangible assets	(41,465)	(11,732)
Acquisitions of long-term financial assets	(149,137)	(235,831)
Other cash flows related to investment transactions	(1,011)	26,200
<b>Net cash flows from investment activities</b>	<b>(980,422)</b>	<b>(330,173)</b>
<b>Cash flows from financing activities:</b>		
Capital increases	8,309	37,515,790
Treasury shares	140,291	(69,477)
Increase (decrease) in repayable advances	7 904,972	(192,497)
<b>Net cash flows from financing activities:</b>	<b>1,053,572</b>	<b>37,253,816</b>
<b>(Decrease) / Increase in cash</b>	<b>(5,561,787)</b>	<b>30,645,797</b>
Cash and cash equivalents at the beginning of the period	37,828,631	11,531,117
Cash and cash equivalents at the close of the period	5 32,266,844	42,176,914



## STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY

(Amounts in Euros)

	Share Capital		Premiums related to the Share Capital	Reserves	Cumulative Income (Loss)	Total Share- holders' Equity
	Shares of Common Stock					
	Number of Shares (note 6)	Amount				
<b>As at January 1, 2012</b>	<b>8,822,745</b>	<b>882,275</b>	<b>17,508,641</b>	<b>13,091,218</b>	<b>(19,775,516)</b>	<b>11,706,617</b>
Net Income					(5,432,929)	(5,432,929)
Increase in capital	4,585,402	458,540	37,057,249			37,515,790
Treasury shares	(9,225)			(69,477)		(69,477)
Share-based payments				1,095,108		1,095,108
<b>Au 30 juin 2012</b>	<b>13,398,922</b>	<b>1,340,815</b>	<b>54,565,890</b>	<b>14,116,849</b>	<b>(25,208,445)</b>	<b>44,815,110</b>
<b>As at January 1, 2013</b>	<b>13,408,147</b>	<b>1,340,815</b>	<b>54,612,601</b>	<b>16,007,235</b>	<b>(32,787,516)</b>	<b>39,173,135</b>
Net Income					(7,906,957)	(7,906,957)
Increase in capital						
Treasury shares	(17,005)			140,291		140,291
Grants of stock warrants			8,309			8,309
Share-based payments				2,050,334		2,050,334
<b>As at June 30, 2013</b>	<b>13,391,142</b>	<b>1.340.815</b>	<b>54,620,910</b>	<b>18,197,860</b>	<b>(40,694,473)</b>	<b>33,465,112</b>



## NOTES TO THE CONDENSED FINANCIAL STATEMENTS

### Note 1 : The Company

Incorporated in 2002, DBV Technologies S.A. ("the Company") develops and markets innovative products for the diagnosis and treatment of allergies, particularly food allergies and allergies in young children.

The Company markets a ready-to-use diagnostic product to detect the allergy to cow's milk in children called *Diallertest*<sup>®</sup>, which was launched in France in 2004. This product is currently distributed in France only through a commercial partner, under an exceptional regulatory status that does not allow it to be promoted. A Phase III clinical trial may start in 2013, the goal of which would be to obtain a marketing authorization for Europe. The Company is currently assessing the relevance of conducting such a study and might decide, if necessary, to stop marketing *Diallertest*<sup>®</sup>.

DBV Technologies is also developing an original electrostatic patch technology, *Viaskin*<sup>®</sup>, for the purpose of developing the cutaneous administration method in specific immunotherapy, or desensitization.

*Viaskin*<sup>®</sup> *Peanut* is the first specific immunotherapy product developed by DBV Technologies. Solid pre-clinical data have already been published. The pharmacological development has been able to be conducted as a result of a vast network of collaborative efforts in the United States and in Europe. A tolerance study (Phase Ib) conducted in the United States demonstrated the innocuousness and high level of tolerance of *Viaskin*<sup>®</sup> *Peanut* in patients with peanut allergies, and the FDA granted a Fast Track designation to the product. In France, the French Health Product Safety Agency (*Agence Française de Sécurité Sanitaire des Produits de Santé*, AFSSAPS) authorized an effectiveness study sponsored by the Paris region public hospitals (*Assistance Publique – Hôpitaux de Paris*, AP/HP). In 2012, an effectiveness study (Phase IIb) was begun in the United States and Europe, with results expected sometime in 2014.

*Viaskin*<sup>®</sup> *Milk* is the second product developed within the field of specific immunotherapy. A Phase II pilot study published by Dupont et al. (JACI 2010) has demonstrated the safety and effectiveness of *Viaskin*<sup>®</sup> *Milk* in children. In 2013, the Company is preparing the launch of a clinical effectiveness study using *Viaskin*<sup>®</sup> *Milk*.

### Major events during the first half 2013

On January 15<sup>th</sup> 2013, DBV Technologies announced that the Company and the French Institute for Agricultural Research-INRA (Molecular Virology and Immunology Unit, VIM-U892) have been awarded a research grant of nearly €600.000 from the French National Research Agency (ANR) to develop an innovative, efficient and safe pediatric 'RSV' bronchiolitis ('RSV') vaccine. RSV-NanoViaSkin is intended to become the world's first non-invasive and adjuvant-free epicutaneous RSV pediatric vaccine.

On March 5<sup>th</sup> 2013, DBV Technologies announced that it entered into a strategic manufacturing agreement with Sanofi to produce *Viaskin*<sup>®</sup>'s Active Pharmaceutical Ingredients (API), such as the peanut protein extract.





As per the agreement, Sanofi will act as DBV's Contract Manufacturing Organization (CMO). In this context, Sanofi will scale-up and validate the production process of Viaskin®'s API and full supply at commercial scale.

DBV will benefit from Sanofi's strong expertise in biologics development and manufacturing in the field of plant extraction and purification of therapeutic proteins to further develop Viaskin®. In addition, the manufacturing site at Aramon (France), which manufactures DBV's APIs, is FDA-approved and has all the necessary capabilities to support the registration of Viaskin® for both the EU and US markets.

On May 7<sup>th</sup> 2013, DBV Technologies announced a partnership with the Jaffe Food Allergy Institute at the Icahn School of Medicine at Mount Sinai (New York) for research related to the mechanism by which epicutaneous immunotherapy (EPIT®) using Viaskin® leads to immune tolerance to food antigens.

On May 16<sup>th</sup> 2013, DBV Technologies and Stallergenes announced that they have entered into a strategic research partnership.

This partnership combines Stallergenes' world class know-how in respiratory allergies with DBV's Viaskin®, a unique platform allowing for epicutaneous desensitization. DBV will conduct all preclinical work, up to proof-of-concept studies using Viaskin® and Stallergenes' aeroallergens. Stallergenes will finance all of DBV's research on these aeroallergens and will have development and commercialization rights. In the coming months, the parties will enter into license agreements for each aeroallergen, defining the opt-in terms for development and commercialization.

On June 6<sup>th</sup> 2013, DBV Technologies announced the appointment of Véronique Foutel as Chief Strategic Marketing Officer, member of the Executive Committee.

On June 20<sup>th</sup> 2013, DBV Technologies announced the 6-, 12- and 18-month efficacy data of Arachild, a study sponsored by Assistance Publique-Hôpitaux de Paris (AP-HP). The analysis of the data shows that two-thirds of children less than 12 years old reach the efficacy endpoints after 18-month treatment with Viaskin® Peanut 100 µg. The serological response observed over the period was robust and strong, implying efficacy of the ongoing desensitization process.

On June 28<sup>th</sup> 2013, DBV Technologies presented six clinical and preclinical presentations on Epicutaneous Immunotherapy (EPIT®) at the European Academy of Allergy & Clinical Immunology & World Allergy Organization & World Allergy & Asthma Congress (EAACI-WAO) in Milan, Italy. DBV's Viaskin® technology was highlighted in six presentations, which included one oral presentation on DBV's currently ongoing phase IIb (VIPES) food challenge methodology, as well as multiple poster presentations on EPIT's immunological impact.

## **Note 2 : Guiding principles and compliance**

### **Preliminary remarks**

The company's accounts are established and presented in euros, unless otherwise stated.

Condensed Half year accounts close on June 30, 2013.

Condensed Half Year accounts have been approved on July 25, 2013 by the Board of Directors.



## General principles and statement of compliance

In compliance with EC regulation n°1606 / 2002 adopted on July 19, 2002 by the European Parliament and European Council the financial statements were prepared in compliance with the IFRS standards as adopted by the European Union in effect as of 31 December 2011, for all the reporting periods presented.

IFRS as adopted by the EC differs in certain aspects to the one published by IASB. Nevertheless, the Company has made sure that the financial information presented in its statements would not have been materially different if presented according to IASB's IFRS framework.

International standards include IFRS norms (*International Financial Reporting Standards*), IAS norms (*International Accounting Standards*) as well as SIC (*Standing Interpretations Committee*) and IFRIC (*International Financial Reporting Interpretations Committee*) interpretations.

Half Year 2013 condensed financial statements have been prepared according IAS 34 –Interim Financial Information, as adopted by the European Union, that allows for selected notes explaining the statements.

Notes do not include the full information required for full year financial statements and must therefore be read jointly with the full year 2012 financial statements.

The Company applied the revised IAS19 norm, applicable as of 1<sup>st</sup> January 2013, applied retrospectively as of 1<sup>st</sup> January 2012. This application constitutes a change in methodology. The impacts on main 2012 indicators would be:

- an increase of 99,900 euros in net result,
- and a decrease of 99,900 euros in Other items of the total profit (loss).

The texts adopted by the EC are available on its website : [http://ec.europa.eu/internal\\_market/accounting/ias\\_fr.htm](http://ec.europa.eu/internal_market/accounting/ias_fr.htm)

## Seasonality

The Company's activities are not subject to any significant seasonality effects in sales.

## Note 3 : Long-term financial assets

(Amounts in euros)

	<u>30/06/2013</u>	<u>31/12/2012</u>
Security deposits	83,365	82,999
Capitalized securities	275,510	275,510
Liquidity contract	174,619	25,848
<b>Total long-term financial assets</b>	<b><u>533,494</u></b>	<b><u>384,357</u></b>

The long-term 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, as well as a liquidity contract. In this context, 17,005 shares have



therefore been deducted from Shareholder's equity as at June 30, 2012 and the cash counterpart maintained in long term .

#### **Note 4 : Other current assets**

The other current assets are broken down as follows

(Amounts in Euros)

	<u>30/06/2013</u>	<u>31/12/2012</u>
Research tax credit	3,651,353	2,522,399
Other tax claims	449,893	355,728
Other receivables	-	45,664
Prepaid expenses	202,169	193,696
<b>Total</b>	<u><b>4,303,415</b></u>	<u><b>3,117,487</b></u>

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

The prepaid expenses correspond mostly to expenses related to rents and insurance.

#### *Research Tax Credits*

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 (*Crédit d'Impôt Recherche*, "CIR"). In compliance with the principles described in Note 3.14 of the Company's December 31, 2012 IFRS financial statements, the Research Tax Credit is posted to the accounts as "other income" during the year with which the eligible research expenditures are associated.

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

- 2010 : € 1.386.989, paid in 2011,
- 2011 : € 1.699.080, paid in 2012,
- 2012 : € 2,522,399, to be paid in 2013.

The Company recorded in its accounts Research Tax Credits in the amount of 1,128,954 euros as at 30 June 2013 and 1,219,847 euros as at 30 June 2012.



### Note 5 : Cash and cash equivalents

The cash and cash equivalents item is broken down as follows:

(Amounts in euros)

	<u>30/06/2013</u>	<u>31/12/2012</u>
Cash	408,623	98,130
Bank overdrafts	-	(519,499)
Investment securities	58,221	-
Term deposits	<u>31,800,000</u>	<u>38,250,000</u>
<b>Total</b>	<b><u>32,266,488</u></b>	<b><u>37,828,631</u></b>

### Note 6 : Capital

The share capital, as of 30 June 2013, is set at the sum of € 1,340,814.70. It is divided into 13,408,147 fully subscribed and paid-up shares with a par value of € 0.10.

This number does not include stock warrants (*Bons de Souscription d'Actions*, "BSAs") and founders' warrants (*Bons de Souscription de Parts de Créateur d'Entreprise*, "BSPCEs") granted to certain individuals, 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 impact of share-based payments on the net income (or loss) is presented in Note 11.

### Note 7 : Borrowings and financial debts

Conditional advances from public institutions are the object of contracts with OSEO and COFACE.

As of 30 June, 2013, 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.

In addition, the Company also benefited over the period from a third financing contract with OSEO, composed of both subsidies and conditional advances.

The portion of the conditional advances for terms longer than one year is posted to long-term liabilities, whilst the portion for terms of less than one year is posted to current liabilities.

The table below presents the details of the debts recorded on the balance sheet by the type of repayable advance (amounts in Euros):



	2nd OSEO contract	3rd OSEO contract	4th OSEO contract	COFACE	Total
<b>Opening Balance Sheet Debt as of 01/01/2012</b>	<b>450,713</b>	<b>246,238</b>	-	<b>122,501</b>	<b>819,452</b>
+ receipts	-	-	-	-	-
- repayments	(200,000)	-	-	-	(200,000)
+/- other transactions	(4,257)	9,438	-	2,322	7,503
<b>Balance Sheet Debt as of 30/06/2012</b>	<b>246,456</b>	<b>255,676</b>	-	<b>124,823</b>	<b>626,955</b>

  

	2nd OSEO contract	3rd OSEO contract	4th OSEO contract	COFACE	Total
<b>Opening Balance Sheet Debt as of 01/01/2013</b>	<b>257,414</b>	<b>249,899</b>	-	<b>126,752</b>	<b>634,065</b>
+ receipts	-	256,000	903,500	-	1,159,500
- repayments	(260,000)	-	-	-	(260,000)
+/- other transactions	2,586	481	-	2,404	5,471
<b>Balance Sheet Debt as of 30/06/2013</b>	-	<b>506,380</b>	<b>903,500</b>	<b>129,156</b>	<b>1,539,036</b>

## Note 8 : Supplier accounts receivable and other current liabilities

### 8.1 Supplier accounts payable and related payables

Of the supplier accounts payable and related payables, no discounting was performed to the extent that the amounts did not present payment terms longer than 1 year at the end of each fiscal year presented.

### 8.2 Other current liabilities

(Amounts in Euros)

	30/06/2013	31/12/2012
Social security contribution liabilities	1,025,314	1,158,362
Tax liabilities	49,768	62,793
Other debts	36,500	67,000
Deferred income	834,469	127,298
<b>Total</b>	<b>1,946,051</b>	<b>1,415,453</b>

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



## Note 9 : Total revenues

Total revenues break down as follows :

(Amounts in euros)

	<u>30/06/2013</u>	<u>30/06/2012</u>
Sales	72,735	71,704
Credit Tax research	1,128,954	1,219,847
Subsidies	134,330	24,535
<b>Total</b>	<b><u>1,336,019</u></b>	<b><u>1,316,086</u></b>

Sales stem from the sale of Diallertest® kits.

## Note 10 : Operating expenses

R&D expenses break down as follows :

	<b>First Half</b>	
<i>(Amounts in euros)</i>	<u>2013</u>	<u>2012</u>
Personnel costs	2,745,687	1,793,643
Sub-contracting, Collaboration, and Consultants	3,127,406	2,637,834
Research Supplies	300,182	261,278
Real Estate Rentals	111,658	122,992
Conferences, Travel expenses	264,160	136,079
D&A	140,501	85,043
Others	134,528	58,034
<b>Total R&amp;D expenses</b>	<b><u>6,824,121</u></b>	<b><u>5,094,902</u></b>

G&A expenses break down as follows:

	<b>First Half</b>	
<i>(Amounts in euros)</i>	<u>2013</u>	<u>2012</u>
Personnel costs	1,737,632	1,333,363
Fees	413,700	120,565
Real Estate Rentals	47,927	57,186
Insurance Coverage	48,972	31,668
Communication, Entertainment and Travel expenses	241,538	141,788
Postal and Telecommunications Expenses	26,291	45,184
Administrative supplies and rental of personal property	57,802	29,858
Others	142,172	36,398
<b>Total G&amp;A</b>	<b><u>2,716,033</u></b>	<b><u>1,796,010</u></b>

### *Personnel costs*

As at 30 June 2013, the Company had 39 employees, compared with 26 as at 30 June 2012.

Personnel costs break down as follows :



(amounts in euros)	<u>30/06/2013</u>	<u>30/06/2012</u>
Wages and salaries	1,634,446	834,856
Social security contributions	741,862	394,707
Performance shares related taxes	-	802,312
Expenses for retirement commitments	56,676	39,457
Payments in shares	<u>2,050,334</u>	<u>1,095,108</u>
<b>Total</b>	<b><u>4,483,318</u></b>	<b><u>3,166,440</u></b>

#### **Note 11 : Share-based payments**

The payments in shares of stock involve all the warrants (BSAs/BSPCEs) and performance shares granted to employees, non-employee members of the Board of Directors, scientific consultants, or service providers.

The warrants granted might be exercised at any time after a vesting period of between 0 and 4 years and become null and void after a period of 10 years from the date they are granted. The acquisition of the warrants by the recipients is not subject to market conditions. The expense representing the benefit granted is posted to the accounts using the straight-line method as a personnel expense over the period of acquisition of the rights.

The cost related to the first half 2013 amounts to € 2,050,335, compared with € 1,095,108 a year earlier.

#### **Note 12 : Financial income & expense**

The financial income and expense are broken down as follows:

(Amounts in euros)	<u>30/06/2013</u>	<u>30/06/2012</u>
Financial income	359,447	212,021
Financial expense	<u>(9,722)</u>	<u>(15,137)</u>
<b>Total</b>	<b><u>349,725</u></b>	<b><u>196,884</u></b>

The financial income is mainly composed of capital gains on the disposals of investment securities. The foreign exchange losses and the expenses related to the accretion of the Oseo and Coface advances constitute the financial expenses.

#### **Note 13 : Contingent liabilities**

No significant changes occurred in contingent liabilities between 31 December 2012 and 30 June, 2013.

#### **Note 14 : 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):



	<u>30/06/2013</u>	<u>30/06/2012</u>
Members of the Board of Directors	183,345	66,425
Directors' fees	20,000	6,000
Payments in shares to the members of the Board of Directors	736,094	435,410
Fees paid to SCP Benhamou Vannerom	-	82,256
<b>Total</b>	<b><u>939,439</u></b>	<b><u>590,091</u></b>

The methods for valuation of the benefit related to share-based payments are presented in Note 11. The agreement with SCP Benhamou Vannerom ended December 31<sup>st</sup>, 2012.

Statement of the debts to related parties as of 30 June:

	<u>30/06/2013</u>	<u>30/06/2012</u>
SCP Benhamou Vannerom	-	-
Directors' fees	36,500	34,000
Retirement pension obligations	46,149	11,163
<b>Total</b>	<b><u>82,649</u></b>	<b><u>45,163</u></b>

#### **Note 15 : Post closing events**

On July 8<sup>th</sup> 2013, DBV Technologies announced the completion of enrollment in its global phase IIb clinical trial, VIPES (Viaskin Peanut's Efficacy and Safety), a 12-month treatment study with Viaskin® Peanut. VIPES started in August 2012 and is being conducted in Europe (France, The Netherlands and Poland) and in North America (Canada and USA) with a total of 22 investigators, who collectively screened and randomized 315 and 221 peanut-allergic subjects respectively. VIPES' patient population includes 113 children (6-11 years), 73 adolescents (12-17 years) and 35 adults (18-55 years). DBV anticipates reporting 12-month topline data during the second half of 2014. Viaskin® Peanut was granted Fast Track designation by the U.S. Food and Drug Administration.





## II - MANAGEMENT DISCUSSION & ANALYSES

### ANALYSIS OF PROFIT & LOSS STATEMENT

The Company's **total revenues** amounted to €1,336,019 and €1,316,086 for the first halves 2013 and 2012 respectively. These revenues were primarily generated by Research Tax Credits, and to a lesser extent, by the sales of *Diallertest*<sup>®</sup>, as well as by subsidies received within the framework of the research projects conducted by the Company.

<i>in euros</i>	First Half	
	2013	2012
Sales	72,735	71,704
Other income	1,263,284	1,244,382
<i>of which Research Tax Credits</i>	1,128,954	1,219,847
<i>of which subsidies</i>	134,330	24,535
<b>Total Revenues</b>	<b>1,336,019</b>	<b>1,316,086</b>

As no R&D expenditure is being capitalized until a marketing authorization is obtained, the Research Investment Credit related to said research programs is, for its part, entirely posted to the accounts as operating revenue. The amounts of financial assistance received by the Company during the periods have been deducted from the calculation of the basis of the Research Tax Credit.

The Company posted, for the first half 2013, net revenues related to Research Tax Credits of €1,128,954 which corresponds to that generated during the first half 2013. Reimbursement of the 2012 Research Tax Credits (ie. €1,386,989) has been requested by the Company in compliance with the E.C. tax treatment of small and medium companies. On the day of issuing this Interim Financial Report, the reimbursement had not yet been received.

The increase in Research Tax Credits over the period reflects the intensification of the R&D efforts related to the preparation of the launch of the Phase IIb ('VIPES) for *Viaskin*<sup>®</sup> *Peanut*.

Sales of *Diallertest*<sup>®</sup>, exclusively distributed in France via a commercial partner, amounted to €72,735 in the first half 2013 compared with €71,704 a year earlier. This diagnostic product is not of strategic importance for the Company, which has as its priority the future marketing products stemming from the *Viaskin*<sup>®</sup> platform.

The **cost of goods sold** therefore corresponds to the cost of a service provider in charge of manufacturing *Diallertest*<sup>®</sup>. Indeed, since the Company does not have the status of a pharmaceutical laboratory, the manufacturing of *Diallertest*<sup>®</sup> has to be entrusted to a third party that does have that status, with notably 'Good Manufacturing Practices ('GMP'). This CMO (Contract Manufacturing Organization) thus acts on behalf of DBV Technologies, which has made the equipment for production of the patches available. Cost of Goods reached €52,546 in the first half 2013, compared with €54,987 a year earlier.

The Company's gross margin generated in the first half 2013 stood at approximately 28% of sales, from 23% a year earlier.



**Research and development expenses** increased significantly by 34% to reach €6,824,121 compared with €5,094,902 a year earlier. These efforts primarily reflect the reinforcement of R&D teams in order to support all on-going development programmes, of which 5 clinical studies over the next 24 months. In addition, the Company out-contracts specific activities, notably analyses, and works with consultants in the context of the various projects in place. This expense category largely contributed to the increase in R&D costs.

The Research and Development expenses break down as follows:

<i>in euros</i>	First Half	
	2013	2012
Personnel costs	2,745,687	1,793,643
Sub-contracting, Collaborations and Consultants	3,127,406	2,637,834
Research Supplies	300,182	261,278
Real Estate Rentals	111,658	122,992
Conferences, Travel expenses	264,160	136,079
D&A	140,501	85,043
Others	134,528	58,034
<b>Total R&amp;D expenses</b>	<b>6,824,121</b>	<b>5,094,902</b>

From one year to the next, this table allows us to note, in particular:

- An increase of 19% in "Sub-contracting, Collaborations and Consultants", which includes in particular, the costs of the providers of services on behalf of DBV Technologies within the framework of the Phase I and Phase IIb ('VIPES') for *Viaskin<sup>®</sup> Peanut*;
- An increase of 53% in personnel costs dedicated to R&D resulting from both an increase in the workforce (30 employees as of June 30, 2013, compared with 21 a year earlier) and the expense related to the valuation of long term incentives (performance shares and warrants: "*bons de souscription de parts de créateur d'entreprise*" or "BSPCEs" and "*bons de souscription d'actions*" or "BSAs"), which increased to €1,024,992 from €834,619 a year earlier;
- The increase in "Conferences, Travel expenses" linked to the increase in headcount.

**General & Administrative expenses** ('G&A') include mainly the administrative personnel costs, the building costs related to the headquarters, and certain fees (such as audit, legal, and consultants' fees). In the first half 2013, G&A expenses reached €2,716,033 compared with €1,796,010 a year earlier, or a 51% increase.



G&A expenses break down as follows:

<i>in euros</i>	First Half	
	2013	2012
Personnel costs	1,737,632	1,333,363
Fees	413,700	120,565
Real Estate Rentals	47,927	57,186
Insurance Coverage	48,972	31,668
Communication, Entertainment and Travel expenses	241,538	141,788
Postal and Telecommunications Expenses	26,291	45,184
Administrative supplies and rental of personal property	57,802	29,858
Others	142,172	36,398
<b>Total G&amp;A</b>	<b>2,716,033</b>	<b>1,796,010</b>

Therefore, the total increase mainly stems from:

- A 30% increase in personnel costs, resulting notably from the change in compensation scheme for the CEO (cf. Note 15.1 of the 2012 Reference Document), as well as the recruitment of new individuals;
- A strong increase in fees (+243%) mainly linked to consultancy expenses in the context of significant contracts negotiated over the period and potential future agreements in discussion, together with investor relations costs.

The **net financial income** reached €349,725 in the first half 2013 compared with €196,884 a year earlier. This item includes the financial revenues on the Company's financial assets on the one hand, and foreign exchange losses as well as undiscounting expenses in connection with the OSEO and COFACE advances, on the other. The change in the financial income in the first half 2013 is primarily explained by a strong increase in financial revenues following the cash received by the Company within the framework of its IPO in March 2012. Consequently, financial income went from €212,021 on June 30, 2012 to €359,447 on June 30, 2013.

Considering the deficits recorded over the last 3 fiscal years, the Company has not posted any **corporate tax expense** to the accounts.

The **net loss** for the first half 2013 amounted to €7,906,957 compared with a €5,432,929 loss for the first half 2012. The loss per share issued (based on the weighted average number of shares outstanding over the period) amounted to €0.59 and €0.48 for the first halves 2013 and 2012 respectively.



## ANALYSIS OF THE BALANCE SHEET

The **non-current fixed assets** include the property, plant, and equipment, the long-term intangible assets, and the long-term financial assets. The non-current fixed assets amounted to €2,183,555 and €1,386,652 on June 30, 2013 and December 31, 2012 respectively. This increase results primarily from the refurbishment of laboratories dedicated to research and industrial development.

The **net current assets** amounted to €36,596,270 and €41,588,165 on June 30, 2013 and December 31, 2012 respectively. This negative variation is explained by cash burn from operating activities, partially compensated by the cash-in of subsidies and repayable advances over the period.

As a result, as of June 30, 2013 the Company's **treasury position** stood at €32,266,844 vs. €37,828,631 as at 31 December 2012.

The net change in the **shareholder's equity** of the Company resulted mainly from the net loss over the period. Therefore, Shareholders' equity reached €33,465,112 as of June 30, 2013 compared with €39,173,135 as of December 31, 2012.

## ANALYSIS OF CASH FLOW STATEMENT

<i>in euros</i>	First Half	
	2013	2012
Net cash flow from operating activities	(5,634,937)	(6,277,846)
Net cash flow from investment activities	(980,422)	(330,173)
Net cash flow from financing activities	1,053,572	37,253,816

**Net cash flow from operating activities** for the first halves 2013 and 2012 stood respectively at €(5,634,937) and €(6,277,846). During the first half 2013, net cash flow from operating activities were slightly reduced compared to 2012, mostly due to a one-off change in working capital requirement.

**Net cash flow from investment activities** significantly increased in the first half 2013 in the context of refurbishing laboratories dedicated to research and industrial development.

**Net cash flow from financing activities** reached €1.1 million in the first half 2013 versus €37.3 million a year earlier following the cash receipt of €37.5 million net consecutive to the IPO of the Company on NYSE Euronext in March 2012.



### III – INFORMATION REGARDING 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):

	<u>30/06/2013</u>	<u>30/06/2012</u>
Members of the Board of Directors	183,345	66,425
Directors' fees	20,000	6,000
Payments in shares to the members of the Board of Directors	736,094	435,410
Fees paid to SCP Benhamou Vannerom	-	82,256
<b>Total</b>	<b><u>939,439</u></b>	<b><u>590,091</u></b>

The methods for valuation of the benefit related to share-based payments are presented in Note 11 of the condensed financial statements. The agreement with SCP Benhamou Vannerom ended 31 December 23012.

Statement of the debts to related parties as of 30 June:

	<u>30/06/2013</u>	<u>30/06/2012</u>
SCP Benhamou Vannerom	-	-
Directors' fees	36,500	34,000
Retirement pension obligations	46,149	11,163
<b>Total</b>	<b><u>82,649</u></b>	<b><u>45,163</u></b>



#### IV – RISK FACTORS

The Company operates in an environment which is undergoing rapid change and exposes its operations to a number of risks, some of which are outside its control. The risks and uncertainties set out below are not exhaustive and the reader is advised to refer to the Company's *Document de Référence 2012* available on its website [www.dbv-technologies.com](http://www.dbv-technologies.com).

- The Company is conducting preclinical and clinical programs intended to lead to the eventual commercialization of therapeutic solutions to treat allergies, in particular food allergies and in young children. The development of a candidate medicine is a long and costly process, carried out in several phases, the outcome of which is uncertain. The aim is to establish the therapeutic benefit of the candidate medicine for one or more given indications.

At each development phase, the Company will present the results of its clinical studies to the authorities of the various countries according to its development plan. Additional requirements could arise concerning the study protocols, patient characteristics, durations of treatment, post treatment follow-up, differences in interpretation of the results, differences between the regulatory agencies of the various countries and requests for additional studies in order to specify certain points or targeting specific populations.

Likewise during clinical trials, the timing of patient recruitment can be uncertain, even if the choice of centers and partners is always selected depending recruitment opportunities. In addition, some requests from regulatory authorities could impact the lead time of patient recruitment.

Moreover, the Company could be unable to establish the proper tolerance, lack of adverse immediate or long-term effects, or the effectiveness of one or more of its therapeutic products in animals and humans. Any failure during any of the various clinical phases for a given indication could delay the development, production and commercialization of the therapeutic product in question or even suspend its development. Similarly, any decision by the health authorities or ethics committees requesting additional trials or studies could delay, or even suspend, the development of the therapeutic products in question.

Even though the local lesions caused by use of the patch have always turned out to be mild, when used on a wider scale, these local effects (such as irritation, local inflammation or eczema) could constitute discomfort for some patients that could lead them to cease the treatment prematurely.

Furthermore, the occurrence of long-term effects or the onset or worsening of pathologies or infections, whether pre-existing or not, that current knowledge does not enable identifying, could delay, or even suspend the development or commercialization of the products in question.

To date, the Company cannot ensure that its current or future developments of candidate medicines will one day be successful, or a fortiori within deadlines compatible with the market's needs. Any failure or delay in developing its therapeutic products could have a material adverse effect on the Company's business, earnings, financial situation and outlook.

Also if, after their marketing authorization (MA), the Company's therapeutic products cause side effects that are unacceptable or unnoticed during the clinical trial period, it would be impossible for it to continue marketing them for all or some of the indications targeted, which could have a material adverse effect on its business, outlook, financial situation, earnings and development.



Lastly, the Company could decide not to market some products in some countries or even not to market its products at all if the market, reimbursement or competition conditions or any other event having occurred during the development phase were to call into question the commercial interest of the product(s) in question.

- In order to strengthen its clinical development program and to increase its visibility within the scientific community, the Company uses, and could continue to use, “support” studies conducted by public or university institutions.

The Company does not sponsor of these studies, it does not handle their steering and follow-up. Accordingly, efficacy results of these studies could be affected by failure to harmonize study protocols. Furthermore, the Company does not have any control over these studies’ protocols, and can therefore not anticipate or ensure the manner in which the results will be obtained, used and/or published, or the occurrence of side effects. Moreover, the Company has no control over the quality of the statistical analysis performed by its institutions.

In the context of these university studies, the Company will not control the publication policy with respect to the results and could be denied use of the results for regulatory or communication purposes by the studies’ sponsors.

- Diallertest® Milk, developed by DBV Technologies, is the first product to diagnose allergies to bovine milk proteins in children currently available on the French market with a temporary exceptional status under regulations.

Given the history of use, marketing authorization in Europe requires a single phase III study to be conducted, the protocol of which was discussed and approved by the European authorities (EMA) as part of a Scientific Advice then a Pediatric Investigation Plan (PIP) procedure. The Company is continuing discussions with the regulatory authorities and would like to adjust this protocol. In light of these discussions, in 2013, it will re-examine the strategic and economic interest of continuing the marketing of Diallertest® Milk.

The marketing of Diallertest® Milk could be suspended, on a final or transitional basis, at any time for strategic reasons and/or at the request of the regulatory authorities.

- The Company is dependent on third parties for the supply of various materials, chemical or biological products (including extract proteins) that are necessary to produce patches for the achievement of its clinical trials or patches diagnosis and, ultimately, its future therapeutic patches.

The supply of the Company in any of these materials and products could be reduced or interrupted. In such a case, the Company may not be able to find other suppliers of materials or chemical or biological products of acceptable quality, in appropriate quantities and at an acceptable cost. If key suppliers or manufacturers were lacking or if the supply of products and materials is reduced or discontinued, the Company may not be able to continue to develop, manufacture and market its products in a timely and competitive manner. In addition, these materials and products are subject to stringent manufacturing requirements and rigorous testing. Delays in the completion and validation of facilities and manufacturing processes of these materials and products in the Company's suppliers could affect its ability to complete clinical trials and to commercialize its products cost-effectively and in a timely manner.



To prevent such situations, the Company intends to diversify its supply sources by identifying a minimum a second source of supply for critical raw materials and materials (natural protein and polymer film with a titanium coating).

If the Company encounters difficulties in the supply of these materials, chemical or biological products, if it was not able to maintain its supply agreements or to establish new agreements to develop and manufacture its products in the future, its business, prospects, financial condition, results and development could be significantly affected.

- Within the framework of its development, the company relies on sub-contractors both for the manufacturing of the patches and for the conduct of the clinical trials. Although the Company has taken into account the risks of default on the part of its sub-contractors or risks of termination of the contractual relationships, and has taken measures intended to provide for these risks, any default on their part could have consequences for the length of, or even the continuation of, the clinical studies, and the quality of the data, which must meet strict standards (Good Clinical Practices, Good Manufacturing Practices) imposed by the supervisory authorities, and therefore delay the marketing of the products.

Such events could have a material adverse effect on the business activity, the prospects, the financial position, the earnings, and the development of the Company.

- Throughout the world, the pharmaceutical industry faces continual changes in its regulatory environment and increased supervision by the relevant authorities and the public, which demand greater guarantees as to the safety and effectiveness of medicines. Furthermore, research incentives have been reduced.

The health authorities, in particular the Food and Drug Administration (FDA) in the United States, have imposed increasingly high demands in terms of the volume of data requested in order to establish a product's effectiveness and safety. These requirements have reduced the number of products authorized. In addition, the products marketed are subject to regular reassessment of the risk/benefit analysis after their authorization. The late discovery of problems not detected at the research stage can lead to marketing restrictions, to the suspension or withdrawal of the product and to a greater risk of litigation.

In parallel, while it is becoming increasingly difficult to put innovative products on the market for the reasons mentioned above, governmental authorities seek to facilitate the entry of generic medicines onto the market of the products already marketed through new regulations seeking to change patent law and the rules on data exclusivity on the key markets.

Insofar as new regulations result in an increase in the costs of obtaining and maintaining authorizations to market products or limit the economic value of a new product for its inventor, the growth prospects of the pharmaceutical industry and of the Company could be reduced as a result.

Furthermore, any clinical study is subject to the prior consent of the health authorities of the countries in which it is planned to conduct the study and of ethics committees; a rejection could impede or stop the Company's clinical development program.

Likewise, for each study, the Company sets up a Data and Safety Monitoring Board; as good clinical practices recommend following the opinions of Data and Safety Monitoring Boards, the latter could lead to premature suspensions or delay product development.





Moreover, depending on the information disclosed to them in the course of a study, in particular on the occurrence of serious adverse events, the health authorities could decide to suspend or prematurely stop the study.

The materialization of one or more of these risks could have a material adverse effect on the business, prospects, financial situation, earnings and growth of the Company.

- In order to finance its activities, the Company has also opted for the Research Tax Credit (CIR - Crédit Impôt Recherche), which consists of the Government offering a tax credit to companies that make significant investments in research and development. The research expenditures that are eligible for the CIR include, in particular, wages and salaries, the depreciation of research equipment, provisions of services sub-contracted to approved research agencies (public or private), and the expenses associated with intellectual property. The Company has received a research tax credit that has been reimbursed and audited by the tax authorities for the years 2008 and 2010.

For the coming years, it cannot be ruled out that the tax authorities may challenge the methods used by the Company to calculate the research and development expenditures or that the CIR might be called into question by a change in the regulations or by a challenge by the tax authorities even if the Company complies with the requirements for documentation and eligibility of the expenditures. If such a situation were to occur, that could have an adverse effect on the earnings, the financial position, and the prospects of the Company.