# HALF YEAR FINANCIAL REPORT 2020



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# I – FIRST HALF OF 2020 CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

# INTERIM CONDENSED STATEMENT OF CONSOLIDATED FINANCIAL POSITION

(thous	sands of euros) <b>Note</b>	6/30/2020	12/31/2019
ASSETS			
Non-current assets			
Intangible assets		42	43
Right-of-use assets related to leases	4	18,872	20,589
Property, plant, and equipment	5	21,697	22,270
Other non-current assets	6	21,100	16,488
Total non-current assets		61,711	59,390
Current assets			
Inventories		3,338	2,038
Other current assets	7	8,745	8,021
Cash and cash equivalents	8	225,859	172,027
Total current assets		237,943	182,085
TOTAL ASSETS		299,654	241,476
	Note	6/30/2020	12/31/2019
LIABILITIES			
Shareholders' equity			
Share capital	9	5,493	4,703
Premiums related to the share capital		861,317	725,460
Reserves		(556,016)	(405,014)
Net (loss)		(86,544)	(153,587)
Total shareholders' equity		224,249	171,563
Non-current Liabilities			
Long-term financial debt	10	731	721
Long-term lease debt	4	17,885	19,579
Non-current provisions	11	785	1,474
Other non-current liabilities		419	71
Total non-current liabilities		19,819	21,845
Current Liabilities			
Bank overdrafts		-	-
Short-term financial debt	10	585	577
Short-term lease debt	4	3,348	3,282
Current provisions	11	12,622	644
Supplier accounts payable	10	21,913	21,368
Other current liabilities	12	17,118	22,197
Total current Liabilities		55,585	48,068
TOTAL LIABILITIES AND SHAREHOLDERS' E	QUITY	299,654	241,476



# INTERIM CONDENSED CONSOLIDATED STATEMENT OF INCOME (LOSS) (thousands of euros, except per share information)

		Six months ended June 30,	
	Note	2020	2019
Operating income			
Revenues	13	-	-
Other income	13	7,559	7,062
Total operating income		7,559	7,062
Operating expenses			
Cost of goods sold		-	-
Research and development	14	(48,341)	(52,238)
Sales and marketing	14	(6,382)	(8,327)
General and administrative	14	(19,415)	(25,825)
Restructuring costs	15	(19,317)	-
Total operating expenses		(93,456)	(86,389)
Operating (loss)		(85,897)	(79,327)
Financial revenues	17	195	491
Financial expenses	17	(840)	(966)
Financial profit (loss)		(645)	(475)
Income tax		(3)	(8)
Net (loss)		(86,544)	(79,810)
Basic/diluted earnings per share (€/share)		(1.62)	(2.43)



# INTERIM CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS) (thousands of euros)

	Six months ended June 30,		
	2020 2019		
Net (loss)	(86,544)	(79,810)	
Actuarial gains and losses on employee benefits, net of corporate tax	(31)	150	
(Loss) directly recognised in shareholders' equity	(31)	150	
Other comprehensive income	374	8	
Total comprehensive (loss)	(86,201)	(79,652)	

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 or loss.



# INTERIM CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (thousands of euros)

			ed June 30,
_	Note	2020	2019
Net profit (loss) for the period		(86,544)	(79,810)
Reconciliation of the net profit (or loss) and the cash used for the operating activities:			
Amortization and depreciation		15,577	2,437
Retirement pension obligations		(720)	233
Expenses related to share-based payments		2,898	8,040
Other elements		807	515
Operating cash flows before change in working capital		(67,982)	(68,584)
Inventories		(1,300)	(516)
Customer accounts receivable		-	-
Other current assets		(6,355)	(7,420)
Supplier accounts payable		1,534	(5,945)
Other current and non-current liabilities		(5,332)	5,296
Change in working capital requirement		(11,452)	(8,585)
Net cash flow used in operating activities		(79,434)	(77,170)
Cash flows used in investing activities			
Acquisitions of property, plant, and equipment		(1,300)	(2,117)
Acquisitions of intangible assets		(1O)	1
Acquisitions of non-current financial assets		(5)	16
Net cash flows from investment activities		(1,315)	(2,100)
Cash flows from financing activities			
Increase in conditional advances		-	-
(Decrease) in conditional advances		17	(904)
Treasury shares		(323)	34
Capital increases, net of transaction costs		136,648	66,531
Repayment of lease liabilities		(1,622)	(1,403)
Interest paid on lease liabilities		(466)	(521)
Other cash flows related to financing activities		(18)	(27)
Net cash flows used in financing activities		134,236	63,710
(Decrease) in cash		53,487	(15,560)
Cash and cash equivalents at beginning period		172,027	122,770
Impact of exchange rate fluctuations		346	55
Cash and cash equivalents at the close of the period	8	225,859	107,265



# INTERIM CONDENSED STATEMENT OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

(thousands of euros)

	Share ca Shares of co Stoc	ipital ommon	ands of euros)			
	Number of shares (note 9)	Amount	Premiums related to the share capital	Reserve	Profit (loss)	Total shareholders' equity
At January 1, 2019	30 157 777	3,016	539,292	(254,946)	(166,076)	121,286
Net (loss)		-	-	-	(79,810)	(79,810)
Foreign exchange translation Profit (loss) directly recognized in shareholders' equity		-	-	8 150	-	8 150
Total profit (loss) directly recognized in shareholders' equity		-	-	158	(79,810)	(79,652)
Allocation of prior (loss)		-		(166,076)	166,076	-
Increase in capital	6 000 000	600	65,931	-	-	66,531
Treasury shares		-	-	122	-	122
Share-based payments		-	-	8,040	-	8,040
At June 30, 2019	36 157 777	3,616	605,223	(412,702)	(79,810)	116,327
At January 1, 2019	30 157 777	3,016	539,292	(254,946)	(166,076)	121,286
Net (loss)		-		(;; =	(153,587)	(153,587)
Foreign exchange translation		-	-	(63)	-	(63)
Profit (loss) directly recognized in shareholders' equity		-	-	529	-	529
Total profit (loss) directly recognized in shareholders' equity		-	-	466	(153,587)	(153,121)
Allocation of prior (loss)		-	-	(166,076)	166,076	-
Increase in capital	16 870 733	1,687	186,169	-	-	187,856
Treasury shares		-	-	619	-	619
Share-based payments				14,923	-	14,923
At December 31, 2019	47 028 510	4,703	725,460	(405,013)	(153,587)	171,563
At January 1, 2020	47 028 510	4,703	725,460	(405,013)	(153,587)	171,563
Net (loss)		-	-	-	(86,544)	(89,387)
Foreign exchange translation		-	-	374	-	374
Profit (loss) directly recognized in shareholders' equity				(31)	-	(31)
Total profit (loss) directly recognized in shareholders' equity		-	-	344	(86,544)	(86,201)
Allocation of prior (loss)		-		(153,587)	153,587	-
Increase in capital	7 898 677	790	135,857	-	-	136,647
Treasury shares		-	-	(658)	-	(658)
Share-based payments		-	-	2,898	-	2,898
At June 30, 2020	54 927 187	5,493	861,317	(556,017)	(86,544)	224,249



#### NOTES TO THE INTERIM CONDENSED 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®.

#### <u>Viaskin™ Peanut</u>

The Company's lead product candidate, Viaskin<sup>™</sup> Peanut, has completed a global Phase III program for the treatment of peanut-allergic patients 4 to 11 years of age. In October 2018, the Company announced its submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for Viaskin<sup>™</sup> Peanut for the treatment of peanut allergy in children 4 to 11 years of age. On December 19, 2018, the Company announced that, after discussions with the FDA, the Company voluntarily withdrew its Biologics License Application ("BLA") for Viaskin™ Peanut in children 4 to 11 years of age. On August 7, 2019, the Company announced the submission of its BLA to the FDA for its investigational Viaskin<sup>™</sup> Peanut immunotherapy for the treatment of peanut-allergic children ages 4 to 11 years. On October 4, 2019, the Company announced that the FDA has accepted the BLA for review. On March 16, 2020, the Company announced that the FDA had informed the Company that during the FDA's ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the FDA communicated that the Advisory Committee meeting to discuss the BLA would no longer take place as previously scheduled on May 15, 2020. The Company promptly submitted additional data analyses that DBV believes addressed the questions put forward by the FDA and asked the FDA to provide feedback on the path forward. These data analyses, which showed that the majority of patients treated with Viaskin™ Peanut achieved sufficient daily application duration to experience clinical benefit, have also been published in two peer-reviewed publications. Following submission of the data analyses in April and requests for discussion, FDA did not provide further information beyond that the data was being reviewed and the target action date of August 5, 2020 remains unchanged.

On January 8, 2020, the Company announced positive topline results of the three-year, open-label extension of the Phase III PEPITES trial (PEOPLE) evaluating the long-term efficacy and safety of investigational Viaskin<sup>™</sup> Peanut in peanut-allergic children ages 4 to 11 years. The results demonstrate long-term clinical benefit as shown by an increase in eliciting dose (ED), which may decrease the chance of reacting to an accidental peanut exposure. After three years, 75.9% (107/141) of patients had increased their ED from baseline, and 51.8% (73/141) of patients reached an ED of at least 1,000 mg peanut protein by year three. The safety profile of Viaskin<sup>™</sup> Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. During PEOPLE, the most common adverse events were mild to moderate skin reactions localized to the administration site and there was no epinephrine use deemed related to treatment. Low discontinuations due to adverse events were observed in the trial. On July 10, 2020, the PEOPLE data were published online in The Journal of Allergy and Clinical Immunology (JACI).

In August 2017, the Company initiated Part A of the EPITOPE (EPIT® in Toddlers with Peanut Allergy) trial, a Phase III trial of Viaskin<sup>TM</sup> Peanut in peanut-allergic toddlers ages one to three. EPITOPE is a two-part, pivotal Phase III clinical trial assessing the safety and efficacy of Viaskin<sup>TM</sup> Peanut 250  $\mu$  g for the treatment of peanut-allergic toddlers one to three years of age. In September 2018, the Company announced that the independent data safety and monitoring board ("DSMB") completed its review of Part A of EPITOPE and recommended that the dose of Viaskin<sup>TM</sup> Peanut 250  $\mu$  g be evaluated in Part B. On October 26, 2018, the Company announced that the first patient was enrolled in Part B of



EPITOPE. This trial is the second Phase III clinical program currently investigating the use of Viaskin<sup>™</sup> Peanut for the treatment of patients with peanut allergy. On June 26, 2020, the Company announced that in Part A, patients in both treatment arms showed consistent treatment effect after 12 months of therapy, as assessed by a double-blind placebo- controlled food challenge and biomarker results. Part A subjects were not included in Part B and the efficacy analyses from Part A were not statistically powered to demonstrate superiority of either dose versus placebo. These results validate the ongoing investigation of the 250 µg dose in this age group, which is the dose being studied in Part B of the study.

#### <u>Viaskin™ Milk</u>

The Company is developing its second product candidate, Viaskin<sup>TM</sup> Milk, for the treatment of cow's milk protein allergy ("CMPA"), in children two to 17 years of age, which received fast track designation from the FDA in September 2016. In November 2014, the Company initiated a multi-center, doubleblind, placebo-controlled, randomized Phase I/II trial to study the safety and efficacy of Viaskin<sup>TM</sup> Milk in 198 patients with Immunoglobulin E ("IgE") mediated CMPA, which the Company refers to as the Milk Efficacy and Safety ("MILES") trial. In June 2015, the Company announced completion of Part A of the MILES trial, or Phase I, and it launched Part B, or Phase II, in October 2015. In February 2018, the Company announced preliminary results from Part B of the MILES trial. Following analyses of the data, the 300  $\mu$  g dose was identified as the dose with the greatest observed clinical activity for children (intent-to-treat, p=0.042). All patients in the open-label extension trial were switched to the 300  $\mu$  g dose for treatment of up to 24 months. Following the Company's announcement on June 26, 2020, DBV plans to focus on Viaskin<sup>TM</sup> Peanut and scale down other clinical programs and pre-clinical spend until DBV has clarity on the path forward with respect to the BLA for Viaskin<sup>TM</sup> Peanut.

#### <u>Viaskin™ Egg</u>

The Company is also working on a third product candidate, Viaskin<sup>™</sup> Egg, for the treatment of patients suffering from hen's egg allergy. Preclinical development for Viaskin<sup>™</sup> Egg commenced in the first half of 2015. Following the Company's announcement on June 26, 2020, DBV plans to focus on Viaskin<sup>™</sup> Peanut and scale down other clinical programs and pre-clinical spend until DBV has clarity on the path forward with respect to the BLA for Viaskin<sup>™</sup> Peanut.

#### Other Viaskin<sup>™</sup> application

In addition to the Company's development programs in food allergies, it is exploring the use of its Viaskin<sup>™</sup> technology for the treatment of inflammatory and autoimmune diseases with high unmet medical need. Human proof-of-concept trials with Viaskin<sup>™</sup> in Eosinophilic Esophagitis ("EoE") and as a booster vaccination against Bordetella pertussis (whooping cough) in healthy adults have been completed. The Company's other earlier stage research programs include vaccination for respiratory syncytial virus, as well as potential treatments for celiac disease and type I diabetes. Following the Company's announcement on June 26, 2020, DBV plans to focus on Viaskin<sup>™</sup> Peanut and scale down other clinical programs and pre-clinical spend until DBV has clarity on the path forward with respect to the BLA for Viaskin<sup>™</sup> Peanut.

# Major events during the first half of 2020

# 1. CONSEQUENCES OF THE COVID-19 PANDEMIC

The recent outbreak of the novel coronavirus COVID-19, which was declared a pandemic by the World Health Organization on March 11, 2020, has led to adverse impacts on the global economies, disruptions of financial markets, and created uncertainty regarding potential impacts to the Company's operations including approval of Viaskin<sup>™</sup> Peanut, our clinical trials, as well as on our clinical trial material distribution system.



In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced the postponement of most inspections of foreign manufacturing facilities and prior approval inspections (PAI). If this situation were to continue and prevent the FDA from conducting its inspections at the Company's contractors' sites, it could have a significant impact on the FDA's ability to review and process the Company's regulatory submissions in a timely manner.

The current clinical trials (including Phase III EPITOPE, EPOPEX, REALISE, PEOPLE) and future clinical trials that the Company is conducting in the United States, Australia and in Europe have been and may continue to be affected by the COVID-19 epidemic. The Company has experienced a decrease in new patients enrolling in the ongoing clinical studies and it has had to adapt the protocols of its clinical trials because patients remain subject to travel restrictions. The Company has developed direct-to-patient shipment of clinical trial materials in Europe and the United States to allow for an uninterrupted supply of clinical trial patients. Apart from this change in the distribution model, there have been no disruptions in the supply chain for conducting clinical trials and the Company believes that it will be able to meet the clinical material needs of its ongoing clinical studies.

Due to containment measures taken in France, the Company's French subcontractors slowed down their activity from March 2020 to May 2020 and some implemented Business Continuity Plans. However, manufacturing facilities remained operational and the Company believes that this pandemic will have a limited impact on the short- and medium-term production of patches for clinical trials, as well as on the launch of Viaskin<sup>™</sup> Peanut, if approved.

Furthermore, the Company is closely monitoring the progress of COVID-19 and its potential impact on the organization. In accordance with public health directives aimed at slowing the spread of COVID-19, the Company has implemented, starting in mid-March 2020, a distance-work plan for all employees. The Company supports all employees by taking advantage of virtual meeting technology and encourages employees to follow the guidelines of local health authorities.

In accordance with the French government measures taken as part of the COVID-19 epidemic, the company has set-up partial activity for certain employees for the months of April and May 2020 and deferred payment of social security contributions. In addition, Bpifrance suspended all repayment, as of March 24, 2020 and for a period of 6 months. Therefore, no reimbursements were made in the first half of 2020.

As of the date of our report, the Company cannot measure the extent, duration or total impact that the COVID-19 pandemic will have on its financial condition and operations. The impact of the COVID-19 pandemic on the Company's financial results will depend on future developments, including the duration and spread of the COVID-19 pandemic and related governmental notices and restrictions. These developments and the impact of COVID-19 on the financial markets and the economy in general are also highly uncertain and the Company may experience adverse impacts to its business as a result of any economic recession or depression that has occurred or may occur in the future.

# 2. CLINICAL PROGRAMS

#### <u>Viaskin™ Peanut</u>

On January 8, 2020, the Company announced positive topline results of the three-year, open-label extension of the Phase III PEPITES trial (PEOPLE) evaluating the long-term efficacy and safety of investigational Viaskin<sup>™</sup> Peanut in peanut-allergic children ages 4 to 11 years. The results demonstrate long-term clinical benefit as shown by an increase in eliciting dose (ED), which may decrease the chance of reacting to an accidental peanut exposure. After three years, 75.9% (107/141) of patients had increased their ED from baseline, and 51.8% (73/141) of patients reached an ED of at least 1,000 mg



peanut protein by year three. The safety profile of Viaskin<sup>™</sup> Peanut was consistent with that observed in the clinical program to date in over 1,000 patients. During PEOPLE, the most common adverse events were mild to moderate skin reactions localized to the administration site and there was no epinephrine use deemed related to treatment. Low discontinuations due to adverse events were observed in the trial.

On February 21, 2020, the Company announced an allergenic products advisory committee meeting from the FDA to be held on May 15, 2020 to discuss the BLA for Viaskin<sup>™</sup> Peanut. On March 16, 2020, the Company announced that the FDA had informed the Company that during the FDA's ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the Advisory Committee meeting to discuss the BLA would no longer take place as previously scheduled on May 15, 2020. The Company promptly submitted additional data analyses that DBV believes addressed the questions put forward by the FDA and asked the FDA to provide feedback on the path forward. These data analyses, which showed that the majority of patients treated with Viaskin<sup>™</sup> Peanut achieved sufficient daily application duration to experience clinical benefit, have also been published in two peer-reviewed publications in June 2020. Following submission of the data analyses in April and requests for discussion, FDA did not provide further information beyond that the data was being reviewed and the target action date of August 5, 2020 remains unchanged.

On June 26, 2020, the Company announced that in Part A of EPITOPE, patients in both treatment arms showed consistent treatment effect after 12 months of therapy, as assessed by a double-blind placebocontrolled food challenge and biomarker results. Part A subjects were not included in Part B and the efficacy analyses from Part A were not statistically powered to demonstrate superiority of either dose versus placebo. These results validate the ongoing investigation of the 250 µg dose in this age group, which is the dose being studied in Part B of the study.

# 3. CHANGE IN THE GROUP'S ORGANIZATION

On January 2, 2020, the Company announced the appointment of Ramzi Benamar as its Chief Financial Officer. He serves as a member of the Executive Committee and reports to Daniel Tassé, Chief Executive Officer of DBV Technologies.

On January 9, 2020, Marie-Catherine Therene was appointed Deputy CEO as DBV's responsible pharmacist (Pharmacien Responsable) in accordance with applicable regulations in France.

On February 6, 2020, the Company announced the appointment of Pascal Wotling as its Chief Technical Operations Officer (CTOO), effective April 1, 2020. Pascal is responsible for manufacturing, supply chain and new product process development, and serves as a member of the Executive Committee, reporting to Daniel Tassé.

On June 26, 2020, the Company announced that given it has not yet received an update from the U.S. FDA regarding its BLA for Viaskin<sup>™</sup> Peanut, it has undergone a comprehensive business review to best position DBV for the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. As a result, the Board of Directors has approved the immediate initiation of a global and comprehensive restructuring plan, which is expected to include a significant reduction in workforce. The Company has initiated, in compliance with French law, the mandatory consultation process with DBV's Social and Economic Committee in France. The Company announced it is contemplating the implementation of cost reduction measures across the organization, while preserving core activities and competencies. Given the absence of clarity from the FDA, DBV is implementing a restructuring plan that will provide the flexibility to continue the BLA review process, prepare to bring Viaskin<sup>™</sup> Peanut to patients, if approved, and preserve the Company's cash runway.



#### 4. FINANCING

On February 4, 2020, the Company announced the closing of an underwritten global offering of an aggregate of 7,500,000 ordinary shares in (i) a public offering of 4,535,581 ordinary shares in the form of 9,071,162 American Depositary Shares ("ADSs") in the United States, Canada and certain countries outside Europe at a public offering price of \$10.25 per ADS (on the basis of an exchange rate of \$1.0999 =  $\in$ 1.00), and (ii) an offering exclusively addressed to qualified investors in Europe (including France) of 2,964,419 ordinary shares at an offering price of  $\in$ 18.63 per ordinary share (together, the "Global Offering").

On March 2, 2020, the Company announced that the underwriters partially exercised their option to purchase 338,687 additional ordinary shares in the form of 677,374 ADSs at an offering price of \$10.25 per ADS, before deducting commissions and estimated offering expenses (the "Option"). The Option closed on March 4, 2020.

Consequently, following partial exercise of the Option, the total number of ordinary shares sold in the global offering was 7,838,687 ordinary shares, including 4,874,268 ordinary shares in the form of 9,748,536 ADSs, bringing the total gross proceeds from the global offering to approximately \$160.7 million (approximately €146.1 million) and net proceeds of €136.6 million.

#### 5. OTHER KEY EVENTS

#### Legal Proceedings

A class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint alleged that the Company and its former Chief Executive Officer, its current Chief Executive Officer, and its Deputy Chief Executive Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The plaintiffs seek unspecified damages on behalf of a purported class of purchasers of our securities between February 14, 2018 and December 19, 2018.

Subsequently, lead plaintiffs were appointed and an amended complaint was filed on January 24, 2020, adding the Company's former Chief Business Officer as a defendant. In March 2020, the Company announced that the FDA identified questions regarding efficacy, including the impact of patch-site adhesion. Following this announcement, the plaintiffs filed an amended complaint on June 12, 2020, adding allegations related to the March 2020 announcement and expanding the class period, from February 14, 2018 to March 16, 2020. The Company believes that the allegations contained in the amended complaint are without merit and intend to defend the case vigorously.



#### Note 2: General principles and statement of compliance

#### 1. Scope of consolidation

As of June 30, 2020, the scope of consolidation is composed of 5 entities, a parent company DBV Technologies SA, a Corporate French venture under French law (*société anonyme*) and has its registered offices located at 177/181 avenue Pierre Brossolette, 92120 Montrouge (France) and its four subsidiaries :

- DBV Technologies Inc. was incorporated in Delaware on April 7, 2014 (the "US subsidiary").
- DBV Australia Pty Ltd. was incorporated in New South Wales, Australia on July 3, 2018 (the "Australian subsidiary").
- DBV Canada Ltd. was incorporated in Ottawa, Ontario on August 13, 2018 (the "Canadian subsidiary").
- DBV Pharma was incorporated in Paris on December 21, 2018 (the "French subsidiary").

The share capital of each of the subsidiaries is wholly owned by DBV Technologies S.A. ("DBV Technologies") and they are fully consolidated using the full consolidation method.

#### 2. GENERAL PRINCIPLES

The interim consolidated condensed financial statements (the "Financial Statements") present the operations of DBV Technologies S.A. and its subsidiaries (the "Group") as of June 30, 2020. DBV Technologies is a Corporate French venture under French law (*société anonyme*) and has its registered offices located at 177/181 avenue Pierre Brossolette, 92120 Montrouge (France).

The interim condensed consolidated financial statements at June 30, 2020 have been prepared under the responsibility of the management of DBV Technologies. These interim condensed financial statements were approved by the Board of Directors of the Company on July 30, 2020.

The interim condensed consolidated financial statements of the Group are expressed in thousands of euros unless stated otherwise.

#### 3. STATEMENT OF COMPLIANCE

International accounting standards include International Financial Reporting Standards (IFRS), International Accounting Standards (IAS), as well as the interpretations issued by the Standing Interpretations Committee (SIC), and the International Financial Reporting Interpretations Committee (IFRIC).

The IFRS as adopted by the European Union differ in certain aspects with the IFRS published by the IASB. Nevertheless, the Group ensured that the financial information for the periods presented would not have been substantially different if it had applied IFRS as published by the IASB.

All text adopted by the European Union are available on the European Commission's website: https://www.efrag.org/Endorsement

The interim consolidated condensed financial statements at June 30, 2020 were prepared in accordance with IAS34 -Interim Financial Reporting, as endorsed by the European Union, which requires the disclosure of selected explanatory notes only.

The condensed financial statements do not include all disclosures required for annual financial statements and should therefore be read in conjunction with the consolidated financial statements for the year ended December 31, 2019.



# Note 3: Accounting principles and methods used at June 30, 2020

These condensed consolidated financial statements are prepared using the same accounting policies and methods as those applied by DBV Technologies at December 31, 2019 (described in Note 3 of the consolidated accounts as of December 31, 2019 published) and in accordance with other standards and interpretations that came into effect on January 1, 2020.

The Company did not elect for early application of the new standards, amendments and interpretations which were adopted by European Union but not mandatory as of January 1, 2020:

- IFRS 17 Insurance contracts;
- Amendments to IFRS 3 Definition of a business;
- Amendments to References to the Conceptual Framework in IFRS Standards.

Management is in the process of evaluating the impact of these standards and amendments application.

#### 3.1. Going concern

Since its inception, the Company has primarily funded its operations with equity financings, and, to a lesser extent, public assistance aimed at supporting innovation as well as payments associated with research tax credit (Crédit d'Impôt Recherche). The Company does not generate product revenue and continues to prepare for the potential launch of its first product in the United States, if approved.

Following the Company's submission of data analyses in April 2020 and requests, FDA did not provide further information beyond that the data was being reviewed and the target action date of August 5, 2020 remained unchanged. Given the absence of clarity from the FDA, DBV announced on June 26, 2020 that it was implementing a restructuring plan that would allow the Company to continue the BLA review process, prepare to launch Viaskin<sup>™</sup> Peanut, if approved, while preserving the Company's cash.

In October 2019, the Company announced the FDA's acceptance of its Biologics License Application ("BLA") for Viaskin<sup>™</sup> Peanut, with a target action date of August 5, 2020. On March 16, 2020, a press release was issued to announce that the FDA had informed the Company that during the FDA's ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the FDA communicated that the Advisory Committee meeting to discuss the BLA would no longer take place as previously scheduled on May 15, 2020. The Company promptly submitted additional data analyses that DBV believes addressed the questions put forward by the FDA and asked the FDA to provide feedback on the path forward. These data analyses, which showed that the majority of patients treated with Viaskin<sup>™</sup> Peanut achieved sufficient daily application duration to experience clinical benefit, have also been published in two peer-reviewed publications.

DBV plans to focus on Viaskin<sup>™</sup> Peanut and scale down other clinical programs and pre-clinical spend. The Company is contemplating the implementation of cost reduction measures across the organization, while preserving core activities and competencies. The revised plan and proposed cost structure assume that Viaskin<sup>™</sup> Peanut will not be launched in the United States within the next 12 months and that the restructuring plan initiated in France will be approved by the French authorities within the planned deadlines. On this basis, DBV now expects that its current balance of cash and cash equivalents of €225.9 million as of June 30, 2020 will be sufficient to fund its operations significantly beyond the prior guidance of the first quarter of 2021 and to support the Company's operating plan for at least the next 12 months. Following feedback from FDA on the Viaskin<sup>™</sup> Peanut BLA review, the Company will provide updated financial guidance.

The Company plans to continue to seek additional capital as it prepares for the launch of Viaskin<sup>™</sup> Peanut, if approved, and continues the research and development efforts for other product candidates



using its Viaskin<sup>™</sup> Platform. The Company may seek to finance its future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings. Considering the situation of the financial markets following the COVID-19 pandemic, the Company cannot guarantee that it will be able to obtain the necessary financing to meet its needs or to obtain funds at attractive terms and conditions. The ongoing global financial crisis caused by the COVID-19 pandemic has already caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to the Company, including reduced ability to raise additional capital when needed and on acceptable terms, if at all.

The Company's interim financial statements have been prepared on a going concern basis as of June 30th, 2020. Consequently, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should we not be able to continue as a going concern.

Refer to the liquidity risk disclosed in the section 4 – Risks factors of the half year 2020 financial report.

#### 3.2. Use of Estimates

The preparation of the Company's Financial Statements requires the management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses. Estimates and assumptions are based on historical experience and other factors that management believes to be reasonable under the circumstances. Estimates and assumptions are measured on an ongoing basis. Actual results may differ from these estimates.

These estimates and judgments mainly involve:

- an estimate of the costs linked with the restructuring plan announced on June 30, 2020, based on the management's best estimate of related social costs, lawyers and consulting fees, or contract termination costs;
- the expected dates of achievement of any performance conditions used to estimate the duration of the spillover from the granting of stock options and free shares;
- the estimate of provision for depreciation of current assets, in particular inventories' work in progress;
- an estimate of the Research Tax Credit based on internal and external expenses incurred by the Company during the period. Only eligible research expenses are included in the calculation of the research tax credit;
- an estimate of time and costs required to complete the collaboration agreement with Nestlé Health Science;
- other employee related accruals such as bonus accruals.

At the date of this report, the Company does not intend to close any facilities in France and in its subsidiaries. As a result, the Company did not identify any asset that may be impaired including lease contracts, laboratory equipment, leasehold improvements, office and computer equipment.



# Note 4: Lease contracts

Analysis of right-of-use assets by category of underlying property are broken down as follows:

(Amounts in thousands of euros)	Real Estate	Other assets	Total
At January 1, 2019	-	-	-
First application of IFRS 16	23,462	330	23,792
Addition of assets	-	130	130
Amortization expense	(3,257)	(125)	(3,382)
Translation adjustments and other	48	-	48
At December 31, 2019	20,253	336	20,589
At January 1, 2020	20,253	336	20,589
Addition of assets	-	(39)	(39)
Amortization expense	(1,638)	(71)	(1,708)
Translation adjustments and other	31		31
At June 30, 2020	18,646	226	18,872

Analysis of maturities of lease liabilities are broken down as follows:

(Amounts in thousands of euros)	6/30/2020	12/31/2019	
Less than One year	3,332	3,281	
One to Five Years	12,374	13,282	
More than Five Years	5,526	6,296	
Total	21,232	22,860	

As of June 30, 2020, and 2019, the interest expense on lease liabilities amounted respectively  $\in$  466 thousand and  $\in$  521 thousand.



#### Note 5: Non-current assets

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Laboratory equipment	18,596	12,432
Building fixtures Office equipment	6,419 818	5,813 808
Computer equipment	1,878	1,694
Property, plant, and equipment in progress	5,744	11,405
Total, gross	33,455	32,152
Total accumulated amortization and depreciation	(11,758)	(9,882)
Total, net	21,297	22,270

As of June 30, 2020 and December 31, 2019, "property plan and equipment in progress" is related to the purchase of materials for the design and development of future industrial machines (Gen 3.2, Gen 3.3 and Gen 4Bis).

#### Note 6: Non-current assets

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Research tax credit	15,027	9,764
Pledged securities	4,315	4,314
Deposits	1,364	1,359
Liquidity contract	393	1,051
Total non-current assets	21,100	16,488

The non-current financial assets are composed of portions repaid in more than one year of research tax credit, security deposits paid to premises' lessors, pledged securities not used as of June 30, 2020 and the liquidity contract.

Under the liquidity contract, 53,101 treasury shares were allocated as a reduction of Shareholders' Equity as at June 30, 2020 with the cash balance being maintained in financial assets.

#### Research tax credit

The Company benefits from the provisions in Articles 244 quater B and 49 septies F of the French Tax Code related to the Research Tax Credit. In compliance with the principles described in Note 3.13 to the financial statements for the year ended December 31, 2019, the Research Tax Credit is posted to the accounts as "Other Income" during the year with which the eligible research expenditures are associated.

Beginning in the fiscal year ending December 31, 2019, Research Tax Credit will now be refunded three years after the tax declaration in the event the Company cannot offset it against corporate income tax due to the loss of its SMEs status under EU law.



The repayable portion of the Research Tax Credit in more than one year is recorded in other non-current assets. Research Tax Credits recorded over the last three fiscal years are presented as follows:

- 2018: €10.8 million (for 12 months), paid in November 2019;
- 2019: €9.8 million (for 12 months)
- 2020: €5.3 million (for 6 months).

The Company recognized as other income a Research Tax Credit in the amount of  $\in$ 5.3 million at June 30, 2020 and  $\in$ 6.0 million at June 30, 2019.

#### Note 7: Other current assets

Other current assets are broken down as follows:

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Other tax claims	4,483	3,995
Prepaid expenses	3,610	3,201
Other receivables	652	825
Total other current assets	8,745	8,021

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

Prepaid expenses are comprised primarily of insurance expenses, as well as legal and scientific consulting fees. Prepaid expenses also include upfront payments which are recognized over the term of the ongoing clinical studies.

#### Note 8: Cash and cash equivalents

The cash and cash equivalents items are broken down as follows:

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Cash	75,354	51,524
Cash equivalent term deposits	150,506	120,503
Total cash and cash equivalent as reported in statement of financial position	225,859	172,027
Bank overdrafts	-	-
Total net cash and cash equivalents as reported in the statement of cash flow	225,859	172,027

Term deposits are immediately convertible into cash at no cost. They are measured using level 1 fair value measurements.

#### Note 9: Capital

The share capital as of June 30, 2020 is set at the sum of  $\in$ 5,492,718.70. It is divided into 54,927,187 fully authorized, subscribed and paid-up shares with a par value of  $\in$ 0.10.

This number does not include share warrants (Bons de Souscription d'Actions, "BSAs"), founders' share warrants (Bons de Souscription de Parts de Créateur d'Entreprise, "BSPCEs"), stock options ("SO") and performance shares ("AGA") granted to certain investors and to certain natural persons, both employees and non-employees of the Company.



Over the six months ended June 30, 2020, the capital increase of €789,868 is linked to:

- the issuance of 59,990 shares in aggregate pursuant to:
  - o the exercise of 24,990 employee warrants and on-employee warrants;
  - the exercise of 35,000 employee's stock options;
- the issuance of 7,838,687 ordinary shares pursuant to the global offering of the first quarter 2020 including the exercise of the underwriters' option to purchase additional ordinary shares.

All the shares give their owners the right to a proportional share of the net income and net assets of the Company. The impact of share-based payments on net income (or loss) is presented in Note 16.

#### Note 10: Financial liabilities

As of June 30, 2020, the Company had a grant from BpiFrance. In 2014, BpiFrance Financement granted an interest-free Innovation Ioan of  $\in$ 3,000,000 to DBV Technologies to help finance the pharmaceutical development of Viaskin<sup>TM</sup> Milk. This amount was received in a single disbursement on November 27, 2014. The planned repayment is scheduled in 20 quarterly repayments of €150,000 each, starting on June 30, 2017. As of March 2, 2020, due to the COVID-19 pandemic, Bpifrance has suspended the repayment for a 6 month period. As a result, the Company did not make any repayments in the first half of 2020.

A conditional advance of  $\in$  1.8 million, granted in 2013 by OSEO to the Company as part of a collaborative research and clinical development in mite allergy for young children has been fully repaid in 2019.

The portion of the conditional advances for terms over 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 thousands of euros)	4th OSEO contract	BPI advance	Total
<b>At January 1, 2019</b> Receipts	624 -	1,854	2,479
Repayments	(624)	(600)	(1,224)
Other transactions	-	44	44
At December 31, 2019		1,298	1,298
Of which - Non-current portion			721
Of which - Current portion			577
At January 1, 2020	-	1,298	1,298
Receipts	-	-	-
Repayments	-	-	-
Other transactions	-	17	17
At June 30, 2020		1,315	1,315
Of which - Non-current portion			731
Of which - Current portion			585



# Note 11: Provisions

Non-current provisions and current provisions break down as follows:

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Non-current provisions	785	1,474
Current provisions	12,622	644
Provisions	13,407	2,118

The table below shows movements in provisions:

(Amounts in thousands of euros)	Pension retirement obligations	Restructuring provisions (See note 15)	Other provisons	Total
At January 1, 2019	1,536	-	1,270	2,806
Increases in provisions	443	-	644	1,087
Used provisions	-	-	(1,270)	(1,270)
Reversals of unused provisions	-	-	-	-
Net interest related to employee benefits, and unwinding of discount	24	-	-	24
Actuarial gains and losses on defined- benefit plans	(529)	-	-	(529)
At December 31, 2019	1,474	-	644	2,118
At January 1, 2020	1,474	-	644	2,118
Increases in provisions	-	11,703	275	11,978
Used provisions	-	-	-	-
Reversals of unused provisions	(726)	-	-	(726)
Net interest related to employee benefits, and unwinding of discount	6	-	-	6
Actuarial gains and losses on defined- benefit plans	31	-	-	31
At June 30, 2020	785	11,703	919	13,407

#### Pension retirement obligation

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

	6/30/2020	12/31/2019
% Social Security contributions	50.0%	50.0%
Salary increases	2.0%	2.0%
Discount rate	0.74%	0.77%



Assumptions for the period ended June 30, 2020 and December 31, 2019:

- Retirement age: 65 years old;
- Terms of retirement: voluntary retirement;
- Life table: TGH05-TGF05;
- Collective agreement: Convention Collective Nationale de l'Industrie Pharmaceutique (National Collective Agreement in the Pharmaceutical Industry);
- Turn-over of the personnel declining with age.

The discount rates come from the corporate Iboxx Corporates AA 10+.

#### Note 12: Supplier accounts payable and other current liabilities

#### 1. SUPPLIER ACCOUNTS PAYABLE AND RELATED PAYABLES

Supplier accounts payable and related payables are not discounted as amounts did not present payment terms longer than 1 year at the end of each fiscal year or period presented.

#### 2. OTHER CURRENT LIABILITIES

(Amounts in thousands of euros)	6/30/2020	12/31/2019
Social debts	15,588	18,100
Deferred revenues	942	3,204
Tax liabilities	329	384
Other debts	259	510
Total other current liabilities	17,118	22,197

The other liabilities include short-term debt to employees including employee termination allowance and benefits as part of the restructuring (See note 15), bonus accruals, as well as social welfare and tax agencies. Bonus accrual estimates include the assumptions of organizational changes implemented by the restructuring plan announced by the Company on June 26, 2020.

In accordance with the French government measures taken as part of the fight against the COVID-19 pandemic, at June 30, 2020, Social debts also include deferred payment of social security contributions.

Deferred revenues include subsidies, conditional advances and current part of deferred revenues from the collaboration agreement with Nestlé Health Science, which amounted to €2.3 million as of June 30, 2020.

#### Note 13: Operating Income

The operating income is broken down as follows:

	Six months ended June 30,		
(Amounts in thousands of euros)	2020	2019	
Revenues	-	-	
Research tax credit	5 263	5,973	
Other operating income	2,295	1,090	
Total operating income	7,559	7,062	

As of June 30, 2020 and June 30, 2019, other operating income is mainly composed by the portion of the upfront fee and milestones agreed under the contract with Nestlé Health Science, which are



deferred over the performance obligation, using the same methods as those described in Note 3.13 to the consolidated financial statements for the year ended December 31, 2019.

#### Note 14: Operating expenses

The research and development expenses are broken down as follows:

	Six months ended June 30,	
	2020	2019
(Amounts in thousands of euros)		
Personnel expenses	14,826	20,419
Sub-contracting, collaborations and consultants	22,684	25,624
Depreciation and amortization	7,391	2,670
Small equipment and supplies	2,107	1,946
Conferences, travel expenses	634	792
Rental	520	333
Others	179	454
Total research and development expenses	48,341	52,238

The sales and marketing expenses are broken down as follows:

	Six months end	Six months ended June 30,	
	2020	2019	
(Amounts in thousands of euros)			
Personnel expenses	3,090	5,961	
Fees	2,832	1,541	
Marketing, tradeshows and travel expenses	95	342	
Depreciation and amortization	268	391	
Others	98	92	
Total sales and marketing expenses	6,382	8,327	

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

	Six months ended June 30,	
	2020	2019
(Amounts in thousands of euros)		
Personnel expenses	5,939	15,809
Fees	8,034	5,947
Insurance policies	2,334	1,071
Depreciation and amortization	980	426
Corporate communication and travel expenses	190	422
Rental	74	164
Others	1,865	1,986
Total general and administrative expenses	19,415	25,825



#### Personnel expenses

As of June 30, 2020, the average headcount of the Group was 311 employees, compared with 323 employees as of June 30, 2019. The average headcount of the first half of 2020 is not materially impacted by the restructuring announced on June 26, 2020.

Personnel expenses are broken down as follows:

	Six months ended June 30,	
(Amounts in thousands of euros)	2020 2019	
Wages and salaries	17,311	25,332
Social security contributions	4,298	7,138
Expenses for pension commitments	457	1,223
Employer contribution to bonus shares	(1,109)	455
Share-based payments	2,898	8,040
Total personnel expenses	23,855	42,188

#### Note 15: Restructuring costs

On June 26, 2020, the Company's Board of Directors approved a restructuring to further extend the Company's operating capital and align personnel towards the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. As of June 30, 2020, the Company initiated a significant reduction of its workforce in U.S. and intends to reduce its workforce in France under the restructuring plan. The Company has initiated, in compliance with French law, the mandatory consultation process with DBV's Social and Economic Committee in France.

The Company estimates that it will incur aggregate charges of approximately €19.3 million based on the management best estimates and including the following costs :

- Employee related expenses including legal and supra-legal allowances, benefits, costs for redeployment aid and accompanying measures;
- Contract termination costs;
- Consulting and lawyers, as well as fees related to psycho-social risks monitoring and social engineering.

The social component of the restructuring plan is expected to be substantially complete by the end of 2020.

At the date of this report, the Company does not intend to close any facilities in France and in its subsidiaries. As a result, as of June 30, 2020, the Company did not identify any asset that may be impaired including lease contracts, laboratory equipment, leasehold improvements, office and computer equipment.

#### Note 16: Share-based payments

The shares-based payments mainly involve stock options and free shares granted to employees and corporate officers.

The stock options granted may 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 expense representing the benefit granted is recorded in the financial statements using the straight-line method as a personnel expense over the vesting period. The acquisition of free shares and



exercise of stock options depend on the existence of an employment contract or holding a corporate office between the recipient and the Company until expiration of the current vesting period as from their initial allocation.

For the six months ended June 30, 2020:

- 94,500 stock options were granted to US employees with exercise prices of €14.64. Contingent upon the holders' continued employment with the Company, these stock options can be vested over a four-year vesting period, on the basis of 25% one year after the grant and 12.5% every 6 months, The exercise will be subject to the following performance condition: approval of Viaskin<sup>™</sup> Peanut by the FDA. The options will be forfeited 10 years after their grant;
- Free shares plans were granted to French employees for a total of 5,000 shares. The definitive allocation of the free shares, subject to a presence requirement, will only occur at the later of the following two dates:
  - expiry of the current vesting period as from their initial allocation and
  - o approval of Viaskin<sup>™</sup> Peanut by the FDA (performance condition).

The IFRS 2 Share based payment for the six months ended June 30, 2020 amounts to  $\leq$ 2.9 million compared to  $\leq$ 8.0 million for the six months ended June 30, 2019

As of June 30, 2020, the expenses associated with share-based compensations include an estimate related to possible requests pertaining to a select number of free share plans from employees in France.

As of June 30, 2020, the total number of ordinary shares that can be created through a full exercise or definitive acquisition, depending on the case, of all of securities giving access to the capital and instruments issued to date amounts to 2,994,173 at a weighted average exercise price of  $\leq$  22.70 (this weighted average exercise price does not include the 693,445 of potential shares resulting from the definitive acquisition of free shares).

# Note 17: Financial revenue and expenses

The following table reflects financial revenue and expenses:

	Six months ended June 30,		
(Amounts in thousands of euros)	2020	2019	
Financial revenues	195	491	
Financial expenses	(840)	(966)	
Total	(645)	(475)	

The financial income is primarily composed of unrealized exchange effect of U.S.-dollar-denominated intercompany advances and capital gains on the disposal of investment securities.

Financial expenses primarily include financial interest related to IFRS 16 lease obligations, foreign exchange losses and expenses related to the accretion of repayable advances.

# Note 18: Off balance sheet commitments

Agreements signed during the first half of 2020 concerning ongoing clinical studies have resulted in an increase in off-balance sheet commitments of approximately  $\in$  7.6 million as of June 30, 2020.

Other operating commitments existing at December 31, 2019 (described in Note 21 to the published consolidated financial statements for the year ended December 31, 2019) had not changed significantly as of June 30, 2020.



#### Note 19: Related parties' transactions

The related parties are exclusively composed of the members of the Board of Directors and the Executive Committee of the Company.

A list of the companies controlled by the Company is presented in note 2. Those companies are fully consolidated and transactions between the parent company and its subsidiaries are eliminated when preparing the consolidated financial statements.

The Company has no significant influence over other companies.

Compensation awarded to the members of the Board of Directors and the Executive Committee of the Company for the six months ended June 30, 2020 totals  $\in$  3.1s million.

	Six months ended June 30,	
(Amounts in thousands of euros)	2020	2019
Short-term benefits	2,751	3,064
Post-employment benefits	31	53
Termination benefits	-	4,092
Share-based payment	324	2,359
Total	3,107	9,568

The valuation terms of the benefit of share-based payments are presented in Note 16.

Statement of the debt towards related parties as of June 30, 2020 is broken down as follows:

As of June 30, 2019, debt toward related parties includes termination benefits in connection with the Executive Committee's organizational changes.

	Six months end	led June 30,
(Amounts in thousands of euros)	2020	2019
Compensation	917	4,588
Pension obligations	99	166
Total	1,016	4,754



#### Note 20: Subsequent events

On July 10, 2020, the Company announced that in Part A, patients in both treatment arms showed consistent treatment effect after 12 months of therapy, as assessed by a double-blind placebocontrolled food challenge and biomarker results. Part A subjects were not included in Part B and the efficacy analyses from Part A were not statistically powered to demonstrate superiority of either dose versus placebo. These results validate the ongoing investigation of the 250 µg dose in this age group, which is the dose being studied in Part B of the study.

The Company evaluated subsequent events that occurred after June 30 2020, through the date of approval of the condensed consolidated financial statements by the Board of Directors and determined that there are no other significant events that require adjustments or disclosure in such condensed consolidated financial statements.



# **II - MANAGEMENT DISCUSSION & ANALYSES**

# ANALYSIS OF PROFIT & LOSS STATEMENT

#### **Operating Revenue**

Our total operating revenue was €7.6 million and €7.1 million for the six months period ended June 30, 2020 and 2019, respectively. This income was mainly generated by our Research Tax Credit and by income recognized under the May 2016 collaboration agreement with Nestlé Health Science.

in thousands of euros	Six months ended June 30,	
	2020	2019
Revenues	-	-
Other income	7,559	7,062
of which research tax Research Tax Credit	5,263	5,973
of which other operating income	2,295	1,090
Total income	7,559	7,062

As R&D expenses are not capitalized until a marketing authorization is obtained, the Research Tax Credit related to such R&D programs is recorded as operating income. Grants received during the periods were deducted from the calculation of the Research Tax Credit.

For the six months ended June 30, 2020 and 2019, we recorded a Research Tax Credit for  $\leq$ 5.3 million and  $\leq$ 6.0 million, respectively. The decrease in revenues related to the Research Tax Credit is mainly due to the decrease in subcontracting and personnel expenses taken into account in the calculation base over the first 6 months of 2020 compared to the first 6 months of 2019.

Beginning in the fiscal year ending December 31, 2019, we will no longer benefit from the immediate reimbursement of the Research Tax Credit due to the loss of our SMEs status under EU law. The Research Tax Credit will now be refunded three years after the tax declaration in the event we cannot offset it against corporate income tax due.

For the first half 2020 and 2019, respectively, we also recorded as other income a portion of the upfront fee and milestones agreed under the contract with Nestlé Health Science, which are deferred over the service obligation period.



#### **Operating Expenses**

As of June 30 ,2020 the Company has undergone a comprehensive business review to best position DBV for the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA given that the Company has not yet received any update from the U.S. FDA regarding its BLA for Viaskin<sup>™</sup> Peanut.

As a result, the Board of Directors has approved the immediate initiation of a global and comprehensive restructuring plan, which is expected to include a significant reduction in workforce.

The related restructuring costs are presented in a separate line of the statement of loss as of June 30, 2020. The Company has also updated its assumptions to take into account the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review and the expected impacts from the announced restructuring on June 26, 2020.

Research and Development Expenses decreased by 7.5% during in the first half 2020 to €48.3 million compared with €52.2 million in the same period in 2019.

in thousands of euros	Six months ended June 30,	
	2020	2019
Personnel expenses	14,826	20,419
Sub-contracting, collaborations and consultants	22,684	25,624
Depreciation and amortization	7,391	2,670
Small equipment and supplies	2,107	1,946
Conferences, travel expenses	634	792
Rental	520	333
Others	179	454
Total research and development expenses	48,341	52,238

The following table summarizes research and development expenses:

Personnel expenses related to research and development decreased by 27.4% compared to the same period in 2019, resulting from a decrease in accrued bonus, retention measures and share-based compensation expense. These decreases are linked with the anticipated changes related to the announced restructuring plan, including the impact of reduced headcount.

The average staff dedicated to Research and Development decreased in comparison to same period in 2019 (from 223 employees in the first half 2019 to 207 employees in the first half 2020). The average staff dedicated to Research and Development is not materially impacted by the restructuring announced on June 26, 2020.

The decrease of 11.5% for sub-contracting, collaborations and consultants mainly relates to expenses incurred in the first half 2019 for the preparation of the Viaskin<sup>™</sup> Peanut BLA for submission to the FDA in August 2019.



Sales and Marketing Expenses decreased by 23.4% during in the first half 2020 to €6.4 million compared with €8.3 million in the same period in 2019. Sales and marketing expenses primarily include payroll for U.S. employees, as well as fees related to pre-commercialization activities for Viaskin<sup>™</sup> Peanut in North America.

The following table summarizes Sales and Marketing expenses:

in thousands of euros	Six months e 30,	Six months ended June 30,	
	2020	2019	
Personnel expenses	3,090	5,961	
Fees	2,832	1,541	
Marketing, tradeshows and travel expenses	95	342	
Depreciation and amortization	268	391	
Others	98	92	
Total sales and marketing expenses	6,382	8,327	

Personnel expenses related to sales and marketing decreased by 48.2% compared to the same period in 2019, resulting from a decrease in accrued bonus, retention measures and share-based compensation expense. These decreases are linked with the change in structuring assumptions used for estimates calculation and to the impacts of the expected headcount reduction related to the announced restructuring plan.

The average staff dedicated to sales and marketing increased in comparison to same period in 2019 (from 30 employees in the first half 2019 to 33 employees in the first half 2020). The average headcount is not materially impacted by the restructuring announced on June 26, 2020.

The increase in fees is mainly due to the increase of fees related to customer engagement as well as marketing tools and services incurred in the first half of 2020 for the preparation of the launch of Viaskin™ Peanut in the U.S., if approved.

General and Administration Expenses were €19.4 million in the first half 2020, compared with €25.8 million in the first half 2019, and include mainly administrative and management personnel costs and certain fees, such as audit, legal and consultants' fees.

The following table summarizes General and Administrative expenses:

in thousands of euros	Six months end	Six months ended June 30,	
	2020	2019	
Personnel expenses	5,939	15,809	
Fees	8,034	5,947	
Insurance policies	2,334	1,071	
Depreciation and amortization	980	426	
Corporate communication and travel expenses	190	422	
Rental	74	164	
Others	1,865	1,986	
Total general and administrative expenses	19,415	25,825	



Personnel expenses related to General and Administrative expenses decreased by 62.4% compared to the same period in 2019, resulting from a decrease in accrued bonus, retention measures and sharebased compensation expense. These decreases are linked with the change in structuring assumptions used for estimates calculation and to the impacts of the expected headcount reduction related to the announced restructuring plan.

The average staff dedicated to General and Administrative expenses increased in comparison to same period in 2019 (from 64 employees in the first half 2019 to 71 employees in the first half 2020). The average headcount is not materially impacted by the restructuring announced on June 26, 2020.

The increase in fees mainly results from the increase of consulting and lawyers' fees in the first half of 2020.

Insurance policies increased by €1.3 million and mainly relates to the increase in Directors and Officers insurance premium.

Restructuring costs were €19.3 million for the six months ended June 30, 2020.

On June 26, 2020, the Company's Board of Directors approved a restructuring to further extend the Company's operating capital and align personnel towards the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. As of June 30, 2020, the Company initiated a significant reduction of its workforce in its subsidiaries mainly in U.S. and intends to reduce its workforce in France under the restructuring plan. The Company has initiated, in compliance with French law, the mandatory consultation process with DBV's Social and Economic Committee in France.

The Company estimates that it will incur aggregate charges of approximately €19.3 million based on the management best estimates and including the following costs:

- Employee related expenses including legal and supra-legal allowances, benefits, costs for redeployment aid and accompanying measures;
- Contract termination costs;
- Consulting and lawyers, as well as fees related to psycho-social risks monitoring and social engineering.

The social component of the restructuring plan is expected to be substantially complete by the end of 2020.

At the date of this report, the Company does not intend to close any facilities in France and in its subsidiaries. As a result, the Company did not identify any asset that may be impaired including lease contracts, laboratory equipment, leasehold improvements, office and computer equipment.

The Company remains focus to preserve its core functions, extend its cash runway and maintain operating latitude to bring Viaskin<sup>™</sup> Peanut to patients in need, if approved.

**Financial (Loss)** was  $\in$  (0.6) million in the first half 2020, compared to a loss  $\in$  (0.5) million in the same period in 2019. This item includes the financial revenues on our financial assets, foreign exchange losses, undiscounting expenses in connection with BpiFrance, and financial expenses on lease obligations.

**Net (Loss)** at the end of June 30, 2020 was  $\in$  (86.5) million compared to  $\in$  (79.8) million at the end June 30, 2019. The loss per share was  $\in$  (1.62) and  $\in$  (2.43) for the six months ended June 30, 2020 and 2019 respectively, based on a weighted average number of shares outstanding of 53,383,299 as of June 30, 2020 and 32,889,633 as of June 30, 2019.



#### ANALYSIS OF THE BALANCE SHEET

**Non-current assets** were  $\in$  61.7 million and  $\in$  59.4 million as of June 30, 2020 and December 31, 2020, respectively, and include long-term intangible assets, rights of use relating to leases, intangible assets and non-current financial assets. The change in **other non-current assets** is mainly due to the recognition of  $\in$  5.3 million related to the Research Tax Credit in the six months ended June 30, 2020.

Net current assets were €237.9 million and €182.1 million as of June 30, 2020 and December 31, 2019, respectively including **net cash and cash equivalents** of €225.9 million as of June 30, 2020 compared to €172.0 million as of December 31, 2019. This variation results mainly from the change in the cash and cash equivalent, driven by the public offering of the first quarter 2020 with net proceeds of €136.6 million, partially offset by cash used in operating activities.

The net change in the Company's **shareholders' equity** mainly results from the losses realized over the period and from the public offering of the first quarter 2020. Shareholders' equity was €224.2 million as of June 30, 2020 compared to €171.6 million at December 31, 2019.

**Current and non-current liabilities** were  $\in$ 75.4 million and  $\in$ 69.9 million as of June 30, 2020 and December 31, 2019, respectively. This change resulted primarily from the recognition of a restructuring actuals and accruals for  $\in$ 19.3 million partially offset by the decrease in other personnel related accruals (including bonus).

# ANALYSIS OF CASH FLOW STATEMENT

in thousands of euros	Six months ended June 30,	
	2020	2019
Net cash used in operating activities	(79,434)	(77,170)
Net cash used in investing activities	(1,315)	(2,100)
Net cash provided by financing activities	134,236	63,710

Net cash used in operating activities was €(79.4) million for the six months ended June 30, 2020, as compared to €(77.2) million for the six months ended June 30, 2019.

Net cash used in investing activities was  $\in$  (1.3) million for the six months ended June 30, 2020, as compared to  $\in$  (2.1) million for the six months ended June 30, 2019. Those investments were mainly for the Company's industrial machinery and equipment, which are expected to be commissioned in order to support the commercialization of Viaskin<sup>TM</sup> Peanut in the United States, if approved.

Net cash from financing activities was  $\in$ 134.2 million for the six months ended June 30, 2020, as compared to  $\in$ 63.7 million for the six months ended June 30, 2019, primarily due to the public offering in the first quarter of 2020.



# **III – INFORMATION REGARDING RELATIONSHIPS WITH RELATED PARTIES**

The compensation awarded to the members of the Company's Board of Directors and Executive Committee and the statement of the debts towards related parties are disclosed in Note 18.



# IV - RISK FACTORS

Since it was first identified in China in December 2019, a novel strain of coronavirus disease (COVID-19) has spread globally, resulting in the declaration of a pandemic by the World Health Organization (WHO) on March 11, 2020. To limit this spread, multiple restrictive measures have been imposed in many countries: quarantines, bans on large public gatherings, closure of places open to the public, restrictions or even bans on movement and the containment of a large part of the world's population. In this context of health crisis caused by the pandemic, the Company has updated some risk factors presented in the 2019 Universal Registration Document. The other main risks that the Company may face in the remaining six months of the financial year are the same to those presented in section 1.4 of the 2019 universal registration document filed with the Autorité des Marchés Financiers ("AMF") on March 20, 2020 (AMF number D.20-0153). All of these risks are likely to occur during the remaining six months of the financial year.

The following risk factors should be read in conjunction with, and are qualified in all respects by, those appearing under the heading "Risk Factors" in our Annual Report on Form 20-F for the year ended December 31, 2019 filed with the Securities and Exchange Commission ("SEC") on March 20, 2020 (the "Annual Report").

# 1. LIQUIDITY RISK REFLECTING ITS ABILITY TO CONTINUE AS A GOING CONCERN

On June 30, 2020, the Company had €225.9 million in cash and cash equivalents compared to €172.0 million of cash and cash equivalents on December 31, 2019. The Company has incurred operating losses and negative cash flows from operations since its inception. Net cash used in operating activities was €79.4 and €77.2 million for the first half 2020 and the first half 2019, respectively. As of June 30, 2020, the Company recorded a net loss of €86.5 million.

Since its inception, the Company has primarily funded its operations with equity financings, and, to a lesser extent, public assistance aimed at supporting innovation as well as payments associated with research tax credit (Crédit Impôt Recherche). The Company does not generate product revenue and continues to prepare for the potential launch of its first product in the United States, if approved.

In October 2019, the Company announced the FDA's acceptance of its Biologics License Application ("BLA") filing for Viaskin<sup>™</sup> Peanut, with a target action date of August 5, 2020. On March 16, 2020, a press release was issued to announce that the FDA had informed the Company that during the FDA's ongoing review of the BLA, it had identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the FDA communicated that the Advisory Committee meeting to discuss the BLA would no longer take place as previously scheduled on May 15, 2020. The Company promptly submitted additional data analyses that DBV believes addressed the questions put forward by the FDA and asked the FDA to provide feedback on the path forward. These data analyses, which showed that the majority of patients treated with Viaskin<sup>™</sup> Peanut achieved sufficient daily application duration to experience clinical benefit, have also been published in two peer-reviewed publications.

Following the Company's submission of data analyses in April 2020 and requests for discussion, FDA did not provide further information beyond that the data was being reviewed and the target action date of August 5, 2020 remained unchanged. Given the absence of clarity from the FDA, DBV announced on June 26, 2020 that it was implementing a restructuring plan that would provide the Company the flexibility to continue the BLA review process, prepare to launch Viaskin<sup>™</sup> Peanut, if approved, while preserving the Company's cash.

DBV plans to focus on Viaskin<sup>™</sup> Peanut and scale down other clinical programs and pre-clinical spend. The Company is contemplating the implementation of cost reduction measures across the organization, while preserving core activities and competencies. The revised plan and proposed cost structure assume that Viaskin<sup>™</sup> Peanut will not be launched in the United States within the next 12



months and that the restructuring plan initiated in France will be approved by the French authorities within planned deadlines. On this basis, DBV now expects that its current balance of cash and cash equivalents of €225.9 million as of June 30, 2020 will be sufficient to fund its operations significantly beyond the prior guidance of the first quarter of 2021 and to support the Company's operating plan for at least the next 12 months. Following feedback from FDA on the Viaskin<sup>™</sup> Peanut BLA review, the Company will provide updated financial guidance.

The Company plans to continue to seek additional capital as it prepares for the launch of Viaskin<sup>™</sup> Peanut, if approved, and seeks to continue the research and development efforts for other product candidates using its Viaskin<sup>™</sup> Platform. The Company may seek to finance its future cash needs through a combination of public or private equity or debt financings, collaborations, license and development agreements and other forms of non-dilutive financings. The Company cannot guarantee that it will be able to obtain the necessary financing to meet its needs or to obtain funds at attractive terms and conditions. The ongoing COVID-19 pandemic has already caused extreme volatility and disruptions in the global capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to the Company, including reduced ability to raise additional capital on acceptable terms when needed, if at all.

The Company's interim financial statements have been prepared on a going concern basis as of June 30, 2020. Consequently, no adjustments have been made to the financial statements relating to the recoverability and classification of the asset carrying amounts or classification of liabilities that might be necessary should we not be able to continue as a going concern.

#### 2. VOLATILITY RISK

The market price of the Company's securities could continue to be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the Company's securities to fluctuate include:

- The results of the Company's preclinical studies and clinical trials or those of its competitors ;
- A potential delay or refusal by the FDA in the United States (or equivalent in another country) to obtain BLA (or equivalent) approval for Viaskin<sup>™</sup> Peanut.
- Evidence of the safety and efficacy of the Company's products and/or those of its competitors;
- Regulatory decisions, in particular those governing the pharmaceutical industry or the food allergy field;
- Changes in the outlook for the Company or its competitors from one period to the next;
- Announcement by the Company or its competitors, of technological innovations or the commercialization of new products;
- Development by the Company or its competitors of initiatives involving partner companies;
- Developments concerning the Company's or its competitors' patents or intellectual property rights, including litigation;
- Announcements of changes to the Company's shareholders;
- Announcements of changes to the Company's management team.

For example, the Company's announcement on October 20, 2017, that it had not reached the minimum confidence interval of 15% as proposed in the Statistical Analysis Plan of its PEPITES clinical study, despite having achieved other criteria, caused its market capitalization to fall by more than 50%.

Furthermore broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments related to the ongoing COVID-19 pandemic, may negatively



affect the market price of the Company's securities, regardless of the Company's actual operating performance.

Additionally, the Company's American Depositary Shares (ADS) are listed on the Nasdaq Global Select Market and ordinary shares in the Company are listed on the Euronext Paris regulated market. Volatility and liquidity in the U.S. market may be different from the French market. The Company cannot predict the impact of its dual listing of ADS and ordinary shares. Should liquidity for shares listed on Euronext Paris not be sustained, the share price may be more volatile and it may become more difficult to buy or sell shares on the Euronext Paris market than on the Nasdaq Global Select Market. Dual listing of the Company's securities in two different currencies (euro and U.S. Dollar) opens the possibility of an arbitrage strategy between the two stock exchanges, which could adversely impact the price of the ADS and the ordinary shares. The sale of the Company's shares or the expectation of their sale may adversely impact the Company's share price. The Company cannot predict the potential impact of its shareholders selling their shares on the market price of its shares.

# 3. THE COMPANY IS DEPENDENT ON OBTAINING AUTHORIZATIONS PRIOR TO MARKETING ITS PRODUCTS, WHICH IS UNCERTAIN

To date, the Company does not have a drug approved for sale and it may never be able to develop a marketable drug or biopharmaceutical product. The Company's business depends almost entirely on the successful clinical development, regulatory approval, and marketing of its product candidates based on Viaskin<sup>™</sup> technology: Viaskin<sup>™</sup> Peanut.

On August 7, 2019, the Company announced that it had filed a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for the treatment of peanut-allergic children 4 to 11 years of age, for Viaskin<sup>™</sup> Peanut, its lead product candidate. This application incorporated additional data regarding manufacturing and quality control procedures formulated by the FDA in December 2018 in response to the Company's first BLA submission in October 2018 which it had voluntarily withdrawn after discussions with the FDA.

On October 4, 2019, the Company announced that the FDA had accepted its Viaskin<sup>™</sup> Peanut BLA filing for review. The target action date provided by the FDA is August 5, 2020.

On February 21, 2020, the Company announced an Allergenic Products Advisory Committee (APAC) meeting to be held on May 15, 2020 to discuss the BLA for Viaskin™ Peanut.

On March 16, 2020, the Company announced that the FDA had informed the Company that during its ongoing review of the BLA for investigational Viaskin<sup>™</sup> Peanut, it has identified questions regarding efficacy, including the impact of patch-site adhesion. Therefore, the APAC meeting to discuss the BLA would no longer take place as previously scheduled on May 15, 2020. The Company promptly submitted additional data analyses that DBV believes addressed the questions put forward by the FDA and asked the FDA to provide feedback on the path forward. These data analyses, which showed that the majority of patients treated with Viaskin<sup>™</sup> Peanut achieved sufficient daily application duration to experience clinical benefit, were recently published in two peer-reviewed publications.

Following submission of the data analyses in April and requests for discussion, FDA did not provide further information beyond that the data was being reviewed and the target action date of August 5, 2020 remained unchanged. Given the Company has not yet received an update from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Viaskin<sup>™</sup> Peanut, the Company has undergone a comprehensive business review to best position DBV for the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. On June 26, 2020, given the absence of clarity from the FDA, DBV announced implementation of a restructuring plan that will provide the flexibility to continue the BLA review process, prepare to bring Viaskin<sup>™</sup> Peanut to patients, if approved, and



preserve the Company's cash runway. DBV plans to focus on Viaskin™ Peanut and scale down other clinical programs and pre-clinical spend.

In addition, in the United States, investigational Viaskin<sup>™</sup> Peanut is being reviewed by the FDA as a biologic under the Federal Food, Drug, and Cosmetic Act, or FDCA, and is evaluated by the Office of Vaccines Research and Review (OVRR), which is also responsible for vaccine evaluation (including COVID-19 vaccines). In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, with requests for Pre-Approval Inspections (PAI) considered on a case-by-case basis. A new PAI has not been scheduled by the FDA for the Viaskin<sup>™</sup> Peanut manufacturing facilities.

The continuation of COVID-19 in several countries, including the United States, and the restrictive measures enacted by the European Union on the movement of persons from certain countries, including the United States, constitute obstacles to the conduct, in the near future, of inspections by the U.S. authorities on manufacturing sites in Europe, including the Contract Manufacturing Organizations (CMOs) sites contracted by DBV.

It is uncertain that Viaskin<sup>™</sup> Peanut will receive regulatory approval from the BLA and be commercialized. It is also possible that the FDA may require the Company to conduct additional clinical trials for Viaskin<sup>™</sup> Peanut.

The clinical trials of DBV's product candidates, as well as manufacturing, and marketing authorization applications to regulators, will be reviewed rigorously by regulatory authorities in the United States and in other countries where the Company intends to develop operations and, if the products are approved, to market them. Before obtaining the necessary regulatory authorizations to market these product candidates, the Company must show, via preclinical and clinical trials, that the product candidate is safe and effective for use in each target indication. This process may take several years and require postmarketing studies and product monitoring, which may generate heavy costs that potentially exceed the external financing currently envisaged by the Company. Only a small percentage of the large number of drugs in development succeed in obtaining all the necessary marketing authorizations. Consequently, even if the Company is able to obtain sufficient financial resources to continue its development and pursue its clinical program, it cannot guarantee that Viaskin<sup>™</sup> Peanut or any other product candidate, will be successfully developed or commercialized.

In particular obtaining BLA approval in the United States is a complex, long, costly, and uncertain process, and the FDA may delay, limit, or refuse to approve Viaskin<sup>™</sup> Peanut for many reasons, including:

- A Global pandemic such as COVID 19;
- FDA may not be able to conduct inspections of the ViankinTM Peanut manufacturing facilities or may have to delay those inspections due to pandemic-related travel restrictions such as Covid-19;
- The Company may not be able to demonstrate that the product candidates are safe and effective for the treatment of food allergies;
- The outcomes of the Company's clinical trials submitted or to be submitted in a BLA may not meet the level of statistical or clinical significance required by the FDA for marketing authorization;
- The FDA may not agree with the number, design, size, conduct, or implementation of those clinical trials;
- The FDA may require additional clinical trials;
- The FDA may not approve the formulation, specifications, or product notice of Viaskin<sup>™</sup> Peanut or Viaskin<sup>™</sup> Milk;



- The FDA may find the data from the preclinical and clinical trials of Viaskin<sup>™</sup> Peanut or Viaskin<sup>™</sup> Milk insufficient to demonstrate that their therapeutic benefit outweighs their safety risks;
- The FDA may disagree with the analysis or interpretation of the data from the preclinical and clinical trials conducted by the Company;
- The FDA may limit the use of the products to a restricted population;
- The FDA or applicable foreign regulatory body may not approve the Company's manufacturing procedures or facilities or those of the third parties to whom they are subcontracted, or may issue inspection results that require major expense or delay; or;
- The FDA may change its approval policies or adopt new regulations.

Any of these factors, many of them beyond the Company's control, may compromise its ability to obtain the necessary regulatory approval to market its product candidates.

The Food and Drug Administration (FDA) has granted "Fast Track" and "Breakthrough Therapy" status to Viaskin<sup>™</sup> Peanut for the treatment of peanut allergies, as well as "Fast Track" status to Viaskin<sup>™</sup> Milk for the treatment of cow's milk protein allergies in children. However, such status may in fact not lead to faster development, regulatory review or marketing authorization than the normal procedure. Furthermore, the FDA may withdraw such status if it believes that the conditions for granting such status are no longer met or no longer justified by the results of the development program.

If global health concerns prevent the FDA or other regulatory authorities from conducting regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to review the Company's regulatory submissions, which could have a material adverse effect on its business.

The Company does not believe that the pandemic will cause, a significant delay in the review and potential approval of the BLA for Viaskin<sup>™</sup> Peanut by the FDA. However, the impact of the COVID-19 pandemic is hard to assess due the rapidly evolving nature of the situation, and it is possible that the review process for the BLA may be delayed.

Current (including Phase III EPITOPE, EPOPEX, REALISE, PEOPLE) and upcoming clinical trials conducted in the United States, Australia and Europe by the Company have been and may continue to be affected by the COVID-19 outbreak. Patient enrollment and randomization have been delayed as patients remain subject to shelter-in-place orders or other restrictions. The Company has initiated direct-to-patient shipment of clinical trial materials in Europe and, in the United States, to ensure uninterrupted supply of clinical trial materials to its clinical trial subjects. Other than this change in its distribution model for clinical trial materials, there has been no disruption in the supply chain that is necessary to conduct its clinical trials, and the Company believes that it will be able to supply the clinical material needs of its ongoing clinical studies.

If COVID-19 continues to spread in the United States, Europe and elsewhere, the Company may experience additional disruptions that could severely impact our clinical trials, including:

- Delays in receiving approval from local regulatory authorities to initiate its planned clinical trials;
- Delays or difficulties in enrolling patients in its clinical trials;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- Delays in clinical sites receiving the supplies and materials needed to conduct its clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require the Company to change the ways in which its clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;



- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- Risk that participants enrolled in its clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including an increase in the number of observed adverse events;
- Interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- Delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- Limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including employee illness, employee's family illness or employee's unwillingness to be in contact with large groups of people; and
- Refusal of the FDA or other regulators to accept data from clinical trials in geographies impacted by the COVID-19 pandemic.

The extent to which the pandemic impacts its business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States, Europe and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, Europe and other countries to contain and treat the disease.

To the extent that the Company's business depends almost entirely on Viaskin<sup>™</sup> technology, should any of these risks materialize, they could have a significant adverse impact on the Company's activity, financial position, earnings, and growth.

# 4. THE COMPANY CANNOT GUARANTEE THE COMMERCIAL SUCCESS OF ITS PRODUCTS

Should the Company initially succeed in obtaining Marketing Authorization (MA) for Viaskin<sup>™</sup> Peanut, Viaskin<sup>™</sup> Milk or its other future therapeutic products, those products may nonetheless take time to gain traction among the medical community, care prescribers, and payers.

The degree of acceptance of each of the Company's products by the market will depend on multiple factors, in particular:

- Demonstration of the clinical efficacy and safety of the product;
- The approved therapeutic indications for the product and all the required warnings;
- Perception of the therapeutic benefits of the product by prescribers, and the Company's ability to educate the medical community on these issues given its limited experience;
- The support of opinion leaders in the field of allergies;
- The potential occurrence of adverse reactions once the MA is obtained;
- The product's ease of use, primarily in terms of its administration (patch);
- The pricing of the treatment;
- The reimbursement policies of governmental agencies and other third parties, and;
- The effective implementation of a scientific publication strategy;

Furthermore, even if the medical community accepts a product as being safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if the Company cannot demonstrate that, based on experience, clinical data, side-effect profiles and other factors its product is preferable to any existing drugs or treatments.

Even if the Company's future products (in particular, Viaskin<sup>™</sup> Peanut) are able to provide a therapeutic response to an as-yet unmet need, weak market penetration, due to one or more of the factors



described above, may adversely impact the Company's business, outlook, financial position, earnings and growth.

In addition, a global pandemic, such as COVID-19, could also have an impact on the commercial success and launch of a new product. As an example, as a result of the COVID-19 pandemic and the multiple restrictive measures enacted by many countries, commercial and medical organizations and pharmaceutical laboratories have suspended in-person interactions with physicians and patients and are restricted to conducting educational and promotional activities virtually. The implementation of these new virtual promotion initiatives to replace sales forces based in medical centers or hospitals is relatively new, and it is difficult to determine how long these operational restrictions related to COVID-19 will remain in place and what the longer-term changes will be in terms of promotion to prescribers and the impact on future sales of a new drug.

The Company's commercial performance also depends on the pricing terms set for its products by competent public commissions and bodies and the terms for their reimbursement by social welfare agencies or private insurers in the countries where the Company intends to market its products. In the current context of tight control of healthcare expenditure and the economic and financial crisis, the pressure on selling prices and reimbursement levels is intensifying, notably due to:

- Price controls introduced by many governments;
- Increasing restrictions on the reimbursement of certain products as part of fiscal policy;
- Increasing difficulty in obtaining and maintaining satisfactory reimbursement for drugs.

All these factors will have a direct impact on the Company's ability to derive profits from the products concerned.

# 5. RISKS RELATING TO GOVERNMENT RESTRICTIONS ON PRICING AND REIMBURSEMENT OF MEDICINES

Government restrictions on pricing and reimbursement, as well as other initiatives by social welfare agencies or payers to limit the reimbursement of healthcare costs may adversely impact the Company's ability to generate revenue should it obtain regulatory approval to market a product.

The control of healthcare costs has become one of the priorities of many governments and the price of drugs has attracted attention on this issue. Governments have shown great interest in implementing cost control programs, notably price controls, reimbursement restrictions, and substitution with generic drugs. The adoption of price and cost control measures, as well as the adoption of more-restrictive policies in jurisdictions where control measures already exist, may limit the Company's potential revenues. The reduction in third-party reimbursement for a product candidate or a decision by a third-party payer not to cover it may reduce the use of that product by physicians and may have a substantial adverse impact on the Company's sales, operating income, and financial position.

For example, in the United States, the first country where the Company intends to market Viaskin<sup>™</sup> Peanut if approved by the regulatory authorities, multiple Congressional inquiries and legislative activities at federal and state level are focusing on, among other things, (i) making drug pricing more transparent; (ii) examining the relationship between manufacturers' prices and programs for patients, and (iii) reforming governmental drug reimbursement methods. At federal level, the Trump administration has released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs. The Blueprint also contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, and incentivize manufacturers to lower the list price of their products. In addition, a global pandemic such as COVID-19 could also have an impact on the price of and access to new drugs.



Other legislative proposals aimed at reforming healthcare reimbursements and government insurance programs in the United States, if approved, may affect the price of future Company products, and reduce the Company's potential revenues.

# 6. THE COMPANY CANNOT GUARANTEE ACCESS TO THE RAW MATERIALS AND PRODUCTS NEEDED TO MANUFACTURE ITS PRODUCTS

The Company is dependent on specialized third parties for its supply of the materials, chemical or biological products (peanuts, protective film, protein extract) needed to make the patches used in clinical trials or diagnostic patches, and, eventually, its future therapeutic patches. The supply of any of these materials may be reduced or interrupted. The Company has put in place mitigation plans such as building up minimum backup inventories.

The Company's supply chain for materials, chemical or biological products needed to make its patches has not been significantly impacted to date by the COVID-19 pandemic. The Company believes that it has sufficient inventories of raw materials, chemicals and other materials to meet short-term demand. However, if the situation were to continue or if a new global health concerns appears, suppliers could encounter difficulties in supplying the Company due to logistical disruptions, reduced production or financial difficulties.

Should the Company encounter supply problems when sourcing these materials, chemical or biological products, or was unable to maintain existing supply agreements or forge new agreements to develop and manufacture its products in the future, its business, outlook, financial position, earnings, and growth could be significantly impacted.

To avoid such situations, the Company has put in place mitigation plans such as building up backup inventories and intends to adjust its supply strategy by identifying at least one alternative source of raw materials and critical materials (natural proteins and titanium-coated polymer film). This may be a long process given its regulatory implications.

# 7. THE COMPANY IS DEPENDENT ON ITS SUBCONTRACTORS

For its development activities, the Company uses subcontractors to make its active ingredients (SANOFI), manufacture its patches (FAREVA), and conduct clinical trials (Contract Research Organizations / "CROs").

Although the Company has taken into account the risk of its subcontractors going bankrupt or breaching their contractual obligations, and has put in place measures to hedge against these risks, any failure on the part of third parties to uphold their obligations to the Company could have consequences on the duration of clinical trials or even the ability to conduct them, on the production and availability of products on the market, and on the quality of data and products that have to meet the strict standards (Good Clinical Practice, Good Manufacturing Practice) imposed by regulatory authorities, and may thus delay the commercialization of its products.

Such events could have a significant adverse impact on the Company's activity, outlook, financial position, earnings, and growth.

Furthermore, some of the Company's main suppliers may have signed or may in the future sign similar agreements with some of its competitors and, due to the competitive environment, may be encouraged not to continue or renew their agreements with the Company on commercially acceptable terms. If such were the case, despite the contractual protections put in place by the Company, its key suppliers may be able to benefit from the information acquired during their contractual relationship with the Company to develop competing treatments.



The COVID 19 pandemic had an impact on the Company's subcontractors, which reduced their activity following the containment measures put in place in France and implement their Business Continuity Plan.

However, the manufacturing facilities have remained operational and the Company believes that this pandemic will have a limited impact on the short- and medium-term production of patches for clinical trials and the launch of Viaskin<sup>™</sup> peanut if approved. In addition, the Company is working closely with its subcontractors to address the production difficulties caused by the pandemic.

# 8. DEPENDENCY ON PRODUCTION EQUIPMENT

The Company depends on its production equipment for the manufacturing of patches, in particular the ES GEN4.0 machine which was developed by the Company and qualified by its subcontractor under its supervision, and the "Cut Pack" machine.

However, any failure of the equipment could interrupt production and have a significant adverse impact on the Company's business, financial situation, and earnings.

The construction of a second ES GEN4.0 machine is in the process of completion to act as a backup production machine. The COVID 19 pandemic did not cause any delay in the production for this back up equipment.

# 9. RISK OF LAWSUIT

The Company operates in compliance with applicable laws and regulations, with the support of its internal legal team and external law firms. However, lawsuits may be filed against the Company by competitors or third parties in the course of business. If the lawsuits succeed, the Company's business and operating earnings may be affected. Even if such lawsuits do not result in a judgment against the Company, the proceedings and the time and resources necessary for their resolution may force the Company to use resources that should have been allocated to the Company's business activities.

For example, in December 2018, the Company announced that it had voluntarily withdrawn its BLA application for Viaskin<sup>™</sup> Peanut following discussions with the FDA about additional data needed regarding its manufacturing and quality control procedures, and ADS price declined significantly as a result. Following this announcement, A class action complaint was filed on January 15, 2019 in the United States District Court for the District of New Jersey, entitled Travis Ito-Stone v. DBV Technologies, et al., Case No. 2:19-cv-00525. The complaint alleged that the Company and its former Chief Executive Officer, its current Chief Executive Officer, and its Deputy Chief Executive Officer violated certain federal securities laws, specifically under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The plaintiffs seeks unspecified damages on behalf of a purported class of purchasers of our securities between February 14, 2018 and December 19, 2018. Subsequently, lead plaintiffs were appointed and an amended complaint was filed on January 24, 2020, adding the Company's former Chief Business Officer as a defendant. In March 2020, the Company announced that the FDA identified questions regarding efficacy, including the impact of patch-site adhesion. Following this announcement, the plaintiffs filed an amended complaint on June 12, 2020, adding allegations relating to the March 2020 announcement and expanding the class period, from February 14, 2018 to March 16, 2020. The Company believes that the allegations contained in the amended complaint are without merit and intend to defend the case vigorously. However, whether or not the plaintiffs' claims have any merit, this type of litigation is often expensive and diverts management's attention and resources, which could adversely affect the operation of the Company's business. If the Company is ultimately required to pay significant defense costs, damages, or settlement amounts, such payments could adversely affect its operations. The Company may be the target of similar litigation in the future. Any future litigation could result in substantial costs and divert management's attention and resources,



which could cause serious harm to the Company's business, operating results, and financial condition. The company maintains liability insurance; however, if any costs or expenses associated with this or any other litigation exceed its insurance coverage, the Company may be forced to bear some or all of these costs and expenses directly, which could be substantial. If the Company is ultimately required to pay significant defense costs and/or damages, such payments could adversely affect its operations.

Furthermore, the Company could be the target of other similar litigation in the future. The Company has corporate liability insurance and director and officer liability insurance. However, if the costs associated with such litigation or any other litigation were to exceed its insurance cover, the Company would be obligated to bear all or some of the costs directly.

# 10. THE COMPANY MAY NOT BE ABLE TO COMMERCIALIZE ITS PRODUCTS BY ITSELF

Given its stage of development, the Company has only limited experience of sales, marketing and distribution of biological drugs. In the near term, the Company will have to acquire marketing skills and develop its sales force, either by itself, or by relying on strategic partners.

On June 26,2020, the Company announced that given the Company has not yet received an update from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Viaskin<sup>™</sup> Peanut, it has undergone a comprehensive business review to best position DBV for the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. As a result, the Board of Directors has approved the immediate initiation of a global and comprehensive restructuring plan, which is expected to include a significant reduction in workforce. The Company has initiated, in compliance with French law, the mandatory consultation process with DBV's Social and Economic Committee in France. In particular, this restructuring led the Company to reduce the commercial structure that it had begun to put in place in the United States.

The Company may therefore not manage to market its products by itself. The Company may in the future have to find partners to market certain products in some or all of its target territories. The Company may not be able to find partners to sell and market its products on terms economically acceptable for the Company.

In any case, when using partners, the Company would not be able to ensure the same degree of control over the resources deployed for marketing as if it were doing the marketing itself. Therefore, these partners would not be able to implement all the resources set out in their agreements with the Company, and in particular not be able to dedicate those necessary for deep market penetration. Budget restrictions or changes of strategy at partners could delay commercialization or reduce its effectiveness or lead to prioritizing the commercialization of other products instead.

Furthermore, the Company cannot guarantee that any of its partners will not develop, or try to develop, a therapeutic approach that competes with the Company's.

Such events could have a significant adverse impact on the Company's operations, outlook, financial position, earnings, and growth.

# 11. THE COMPANY MAY LOSE KEY STAFF AND NOT BE ABLE TO ATTRACT NEW QUALIFIED PEOPLE

Given its field of activity in biotechnology and the necessity of fast development in a fiercely competitive market, the Company's success largely depends on the work and expertise of its qualified staff. The temporary or long-term unavailability of such people could alter the Company's ability to achieve its objectives, particularly by depriving it of their know-how and technical expertise.



In the context of the ongoing COVID-19 pandemic, the safety of the Company's employees, partners, subcontractors and stakeholders remains an absolute priority. In alignment with public health guidance designed to slow the spread of COVID-19, as of mid-March 2020, the Company has undertaken to adapt its working methods to provide its staff with necessary protections. For employees whose presence on site is not required, in particular support functions in France and the United States, the Company has implemented remote work plans. If the COVID-19 pandemic is prolonged or worsens, it could, however, lead to a potential decrease in the commitment of the employees as a result of short-time work or long periods of telework during periods of containment.

Furthermore, on June 26, 2020, the Company announced that given the Company has not yet received an update from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Viaskin<sup>™</sup> Peanut, it has undergone a comprehensive business review to best position DBV for the possibility of a delay in timelines for the Viaskin<sup>™</sup> Peanut BLA review. As a result, the Board of Directors has approved the immediate initiation of a global and comprehensive restructuring plan, which is expected to include a significant reduction in workforce. The Company has initiated, in compliance with French law, the mandatory consultation process with DBV's Social and Economic Committee in France.

However, as the Company does not yet have any products on the market or any sales, attracting qualified personnel and retaining them is more complex than it might for companies at a more developed stage. The Company's inability to attract or retain key staff could prevent it from achieving its overall objectives thereby significantly adversely impacting its operations, earnings, financial situation, and outlook.

#### 12. CYBERSECURITY, AND INFORMATION SYSTEM CONTINUITY AND PERFORMANCE RISK

Given its size, organizational structure and field of activity, any failure or malfunction, including those due to cybercrime, equipment, software applications or communication networks, especially ERP, and the electronic messaging system, could disrupt operations and entail financial loss for the Company. In addition, as a result of the COVID-19 pandemic, the Company may face increased risks of a cybersecurity breach due to its reliance on internet technology and the number of its employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities.

Consequently, with the growth of cybercrime, the security of information systems is a major challenge for the Company, particularly in terms of data protection, R&D and production know-how, its future customers, its employees and patents. The Company has an IT Department whose mission is to ensure the availability, continuity and performance of the IT services provided, to put in place a riskmanagement based IT security program to guarantee the control and protection of information (confidentiality, integrity). In addition, the Company launched a major training and awareness campaign for employees related to cybersecurity in light of current remote work arrangements.

However, in the case of a successful cyberattack on its IT systems, the Company may be the victim of theft of confidential data, personal data, damage to its reputation or image, or total or partial interruption of its operations. The development of new products could also be affected, adversely impacting the Company's reputation, financial position, and competitive rights and advantages.

