



## Press Release

Montrouge, France, August 2, 2021

# DBV Technologies Reports Second Quarter 2021 Financial Results and Recent Business Developments

### Business Highlights:

- **Viaskin Peanut US:** DBV submitted the protocol for the 6-month adhesion and safety study of the modified patch (STAMP), to the U.S. Food and Drug Administration (FDA) and is awaiting feedback.
- DBV completed a trial in healthy adult volunteers to evaluate the adhesion of five modified Viaskin Peanut patches (CHAMP)—two top performers were selected as finalists.
- DBV initiated PREQUAL, a Phase 1 study in healthy adult volunteers to optimize the allergen sample collection methodologies and validate the assays DBV intends to use in EQUAL.
- **Viaskin Peanut EU:** DBV received from the European Medicines Agency (EMA) Day 180 list of outstanding issues. The review of the Viaskin Peanut Marketing Authorization Application (MAA) is progressing according to established EMA processes and ongoing conversations with the EMA.
- **Class Action Complaint:** The U.S. District Court, District of New Jersey entered an order granting DBV's Motion to Dismiss the Second Amended Class Action Complaint without prejudice.
- **Cash and Budget Measures:** DBV continues to exercise budget discipline measures. Based on its current assumptions, DBV expects that its current cash and cash equivalents will support its operations until the second half of 2022.

DBV Technologies S.A. (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter of 2021. The quarterly financial statements were approved by the Board of Directors on July 30, 2021.

“DBV has continued to prioritize the advancement of Viaskin Peanut’s regulatory dossier. In 2Q 2021, we have made significant progress in developing and selecting modified Viaskin Peanut patches,” said Daniel Tasse, Chief Executive Officer, DBV Technologies. “The two final modified patches demonstrate stronger adhesion as compared to the current system while preserving the structure of the occlusion chamber. Further, DBV advanced our clinical study efforts. We initiated a Phase I study intended to support EQUAL and submitted the STAMP study protocol to the FDA. In parallel, DBV has remained diligent about spend and I am confident that



our cash on hand as of June 30, 2021 will support our operations until the second half of 2022.”

## Recent Business Developments

### Viaskin Peanut US:

In 2Q 2021, DBV completed CHAMP (Comparison of adHesion Among Modified Patches), a trial in healthy adult volunteers to evaluate the adhesion of five modified Viaskin Peanut patches in order to identify the top performers. Based on the adhesion parameters studied, DBV was pleased to learn that all modified Viaskin Peanut patches demonstrated better adhesion performance as compared to the current Viaskin Peanut patch. DBV then selected two modified patches that performed best out of the five modified patches studied for further development.

The difference between the two selected patches is their shape—one is circular and the other is rectangular with rounded corners. They are both approximately 50% larger than the current patch but maintain the same structure of the occlusion chamber (i.e., foam ring and backing). DBV also conducted advisory boards with patient caregivers and key opinion leaders to obtain qualitative feedback on the consumer experience with both patches.

DBV submitted the protocol for STAMP (Safety, Tolerability and Adhesion of Modified Patches), the 6-month adhesion and safety study of the modified patch, to the FDA in 2Q 2021 and is currently awaiting feedback.

Earlier this quarter, DBV initiated PREQUAL, a Phase 1 study in healthy adult volunteers to optimize the allergen sample collection methodologies and validate the assays DBV intends to use in EQUAL (EQUivalence in the Uptake of ALLergen). DBV continues to work closely with FDA on how to best demonstrate the protein transport comparability of the modified patch (mVP) to the reference patch (cVP).

### Viaskin Peanut EU:

DBV received from the EMA Day 180 list of outstanding issues. The review of the Viaskin Peanut Marketing Authorization Application (MAA) is progressing according to established EMA processes and ongoing conversations with the EMA.

Many of EMA's Objections and Major Objections have been answered; One Major Objection remains. DBV will provide a response to address the outstanding issues, including the mentioned Major Objection.



Based on the average length of an EMA evaluation of an MAA, DBV estimates the EMA could issue its decision on potential marketing authorization for Viaskin Peanut in the fourth quarter of 2021 or the first quarter of 2022.

**Class Action Complaint:**

As previously disclosed, a class action complaint was filed in January 2019 in the U.S. District Court, District of New Jersey, alleging that the Company and certain current and former executive officers violated certain U.S. federal securities laws. On July 29, 2021, immediately after a hearing, the Court entered an order granting the Company's Motion to Dismiss the Second Amended Class Action Complaint without prejudice. The Court indicated that the Second Amended Complaint was deficient in a number of ways and granted Plaintiffs until September 30 to amend the complaint to try to cure the deficiencies.

**Financial Highlights for the Second Quarter and the 6 Months Ended June 30, 2021<sup>1</sup>**

**Cash and Cash Equivalents** as of June 30, 2021 were \$125.5 million, compared to \$196.4 million as of December 31, 2020 and \$152.5 million as of March 31, 2021. The net decreases of respectively \$27.0 million and \$70.9 million for the quarter and six months ended June 30, 2021 were primarily due to cash used in operating activities and the effect of exchange rates on cash and cash equivalents. Excluding restructuring amounts paid of \$6.3 million in the first half of 2021, the cash used in operating activities amounts to \$(60.2) million under U.S. GAAP and \$(57.8) million under IFRS, reflecting the Company's continued implementation of budget discipline measures. Based on its current assumptions, DBV expects that its current cash and cash equivalents will support its operations until the second half of 2022.

**Operating Income** is primarily generated from DBV's Research Tax Credit (French Crédit Impôt Recherche, or CIR) and from revenue recognized by DBV under its collaboration agreement with Nestlé Health Science. Operating income was \$(1.5) million for the quarter ended June 30, 2021 and \$1.5 million for the six months ended June 30, 2021, compared to \$3.6 million and \$8.3 million respectively for the three months ended and six months ended June 30, 2020. The decrease in operating

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<sup>1</sup> The Company's interim consolidated financial statements for the 6 months ended June 30, 2021 are prepared in accordance with both generally accepted accounting principles in the U.S. ("U.S. GAAP") and International Financial Reporting Standards ("IFRS") as adopted by the European Union. Unless otherwise indicated, the financial figures presented in the Q2 Financial Highlights comply with both U.S. GAAP and IFRS financial statements. Differences between U.S. GAAP and IFRS consolidated financial statements are mainly due to discrepancies arising from the application of lease accounting standards.



income is primarily attributable to the revision of the revenue recognized under Nestlé's collaboration agreement, as the Company updated its measurement of progress of its Phase II clinical study conducted as part of the contract due to recruitments' delays.

## Operating expenses

(\$ in thousands)	U.S. GAAP <sup>2</sup>		U.S. GAAP <sup>2</sup>		IFRS <sup>3</sup>	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020	2021	2020
<b>Operating expenses :</b>						
Research and development	\$ (20,179)	\$ (21,932)	\$ (42,343)	\$ (49,464)	\$ (42,184)	\$ (49,245)
Sales & marketing	(1,198)	778	(1,927)	(6,519)	(1,905)	(6,461)
General & administrative	(8,269)	(8,862)	(17,951)	(19,975)	(17,941)	(19,914)
Restructuring	-	(21,288)	-	(21,288)	-	(21,288)
<b>Total Operating expenses</b>	<b>\$ (29,646)</b>	<b>\$ (51,305)</b>	<b>\$ (62,221)</b>	<b>\$ (97,246)</b>	<b>\$ (62,030)</b>	<b>\$ (96,908)</b>

**Operating Expenses** for the three months ended June 30, 2021, were \$(29.6) million, compared to \$(51.3) million for the three months ended June 30, 2020, each under U.S. GAAP. For the six months ended June 30, 2021, operating expenses were \$(62.2) million under U.S. GAAP and \$(62.0) million under IFRS, compared to \$(97.2) million and \$(96.9) million under U.S GAAP and IFRS, respectively, for the six months ended June 30, 2020. The decrease in operating expenses for both periods is mainly attributable to the decrease in external clinical-related expenses and professional fees due to the budget discipline measures taken by DBV, as well as the decrease in employee-related costs, which is directly related to the workforce reduction DBV implemented as part of its 2020 global restructuring plan.

Excluding share-based payments expenses, employee-related costs decreased by \$9.7 million, from \$23.1 million for the six months ended June 30, 2020 to \$13.4 million for the six months ended June 30, 2021, a 42% decrease, compared to a 64% decrease of the average number of headcounts between the two periods (111 and 311 full-time equivalent employees for the six months ended June 30, 2021 and 2020 respectively). As of June 30, 2021, DBV had 97 employees.

<sup>2</sup> Unaudited financial statements prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").

<sup>3</sup> Unaudited financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union.



## Net Loss and Net Loss Per Share

	U.S. GAAP <sup>4</sup>		U.S. GAAP <sup>4</sup>		IFRS <sup>5</sup>	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020	2021	2020
Net (loss) (\$ in thousands)	\$ (30,654)	\$ (48,203)	\$ (60,103)	\$ (89,115)	\$ (60,241)	\$ (89,291)
Basic / diluted net loss per share (\$/share)	\$ (0.56)	\$ (0.88)	\$ (1.09)	\$ (1.67)	\$ (1.10)	\$ (1.67)

Net loss was \$(30.7) million for the three months ended June 30, 2021, compared to \$(48.2) million for the three months ended June 30, 2020.

Net loss per share (based on the weighted average number of shares outstanding over the period) was \$(0.56) and \$(0.88) for the three months ended June 30, 2021 and 2020, respectively.

For the six months ended June 30, 2021, net loss was \$(60.1) million and \$(60.2) million under U.S. GAAP and IFRS, respectively. Net loss per share was \$(1.09) under U.S. GAAP and \$(1.10) IFRS.

DBV will host a conference call and live audio webcast on Monday, August 2, 2021, at 5:00 p.m. ET to report second quarter 2021 financial results and provide a corporate update.

This call is accessible via the below teleconferencing numbers, followed by the reference ID: 50184237.

- United States: (866) 939-3921
- Canada: (866) 215-5508
- United Kingdom: 0808 238 9578
- France: 0805 102 604

A live webcast of the call will be available on the Investors & Media section of the Company's website: <https://www.dbv-technologies.com/investor-relations/>. A replay of the presentation will also be available on DBV's website after the event.

<sup>4</sup> Unaudited financial statements prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").

<sup>5</sup> Unaudited financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union.



CONDENSED STATEMENT OF CONSOLIDATED FINANCIAL POSITION (unaudited)  
(\$ in thousands)

	U.S. GAAP <sup>6</sup>		IFRS <sup>7</sup>	
	June 30, 2021	December 31, 2020	June 30, 2021	December 31, 2020
<b>Assets</b>	\$ 200,584	\$ 272,246	\$ 200,294	\$ 272,019
<i>of which cash and cash equivalents</i>	125,484	196,352	125,484	196,352
<b>Liabilities</b>	57,565	66,754	57,565	66,754
<b>Shareholders' equity</b>	\$ 143,019	\$ 205,491	\$ 142,729	\$ 205,265
<i>of which net result</i>	(66,097)	(159,555)	(60,241)	(159,374)

CONDENSED STATEMENT OF CONSOLIDATED OPERATIONS AND  
COMPREHENSIVE LOSS (unaudited)  
(\$ in thousands, except per share data)

	U.S. GAAP <sup>6</sup>		U.S. GAAP <sup>6</sup>		IFRS <sup>7</sup>	
	Three months ended June 30,		Six months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020	2021	2020
<b>Revenue</b>	\$ (1,488)	\$ 3,610	\$ 1,453	\$ 8,330	\$ 1,453	\$ 8,330
<b>Operating expenses :</b>						
Research and development	(20,179)	(21,932)	(42,343)	(49,464)	(42,184)	(49,245)
Sales & marketing	(1,198)	,778	(1,927)	(6,519)	(1,905)	(6,461)
General & administrative	(8,269)	(8,862)	(17,951)	(19,975)	(17,941)	(19,914)
Restructuring	-	(21,288)	-	(21,288)	-	(21,288)
<b>Total Operating expenses</b>	<b>(29,646)</b>	<b>(51,305)</b>	<b>(62,221)</b>	<b>(97,246)</b>	<b>(62,030)</b>	<b>(96,908)</b>
Financial Income (Expenses)	46	(506)	261	(196)	(68)	(710)
Income tax	434	(3)	404	(3)	404	(3)
<b>Net (loss)</b>	<b>\$ (30,654)</b>	<b>\$ (48,203)</b>	<b>\$ (60,103)</b>	<b>\$ (89,115)</b>	<b>\$ (60,241)</b>	<b>\$ (89,291)</b>
Basic/diluted Net loss per share attributable to shareholders	\$ (0.56)	\$ (0.88)	\$ (1.09)	\$ (1.67)	\$ (1.10)	\$ (1.67)

<sup>6</sup> Unaudited financial statements prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").

<sup>7</sup> Unaudited financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union.



CONDENSED STATEMENT OF CONSOLIDATED CASH FLOW (unaudited)  
(\$ in thousands)

	U.S. GAAP <sup>8</sup>		IFRS <sup>9</sup>	
	Six months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Net cash flow used in operating activities	\$ (66,503)	\$ (89,848)	\$ (64,101)	\$ (87,585)
Net cash flows used in investing activities	(13)	(1,450)	(13)	(1,449)
Net cash flows provided by (used in) financing activities	1,071	150,672	(1,336)	148,398
Effect of exchange rate changes on cash and cash equivalents	(5,423)	289	(5,418)	299
<b>Net (decrease) / increase in cash and cash equivalents</b>	<b>(70,868)</b>	<b>59,663</b>	<b>(70,868)</b>	<b>59,663</b>
Net cash and cash equivalents at the beginning of the period	196,352	193,255	196,352	193,255
<b>Net cash and cash equivalents at the end of the period</b>	<b>\$ 125,484</b>	<b>\$ 252,917</b>	<b>\$ 125,484</b>	<b>\$ 252,917</b>

### About DBV Technologies

DBV Technologies is developing Viaskin™, an investigational proprietary technology platform with broad potential applications in immunotherapy. Viaskin is based on epicutaneous immunotherapy, or EPIT™, DBV's method of delivering biologically active compounds to the immune system through intact skin. With this new class of non-invasive product candidates, the Company is dedicated to safely transforming the care of food allergic patients. DBV's food allergies programs include ongoing clinical trials of Viaskin Peanut. DBV Technologies has global headquarters in Montrouge, France, and North American operations in Summit, NJ. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345), part of the SBF120 index, and the Company's ADSs (each representing one-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

### Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding DBV's forecast of its cash runway, DBV's

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anticipated budget discipline measures, DBV's planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies, and the outcome of any litigation. These forward-looking statements and estimates are not promises or guarantees and involve substantial risks and uncertainties. At this stage, DBV's product candidates have not been authorized for sale in any country. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, including the impact of the COVID-19 pandemic, and DBV's ability to successfully execute on its budget discipline measures. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in DBV's regulatory filings with the French Autorité des Marchés Financiers ("AMF"), DBV's filings and reports with the U.S. Securities and Exchange Commission ("SEC"), including in DBV's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 17, 2021, and future filings and reports made with the AMF and SEC by DBV. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, DBV Technologies undertakes no obligation to update or revise the information contained in this Press Release.

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