



Montrouge, France, October 26, 2021

# DBV Technologies Reports Third Quarter 2021 Financial Results and Recent Regulatory Developments

DBV Technologies S.A. (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today reported financial results for the third quarter of 2021. The quarterly financial statements were approved by the Board of Directors on October 26, 2021. The Company also provided regulatory updates from the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for Viaskin<sup>TM</sup> Peanut.

### US Regulatory Update:

On October 14, 2021, DBV received communication from the FDA concerning the STAMP protocol submission of May 6, 2021. The FDA has requested a stepwise approach to DBV's modified Viaskin Peanut (mVP) development program. The FDA would like to review the data from DBV's protein uptake release study prior to providing additional comments on the STAMP protocol design.

In its communication, FDA stated that guidance is forthcoming on how best to demonstrate the protein uptake comparability of the mVP to the reference or current patch (cVP).

The STAMP trial will not be initiated until DBV receives complete feedback from the FDA.

"DBV is working hard to find an efficient and timely path forward. On behalf of patients and providers urgently awaiting a therapeutic advancement in treating peanut allergy, DBV will continue to pursue our goal of bringing Viaskin Peanut to the food allergy community," said Daniel Tasse, Chief Executive Officer, DBV Technologies.

### **EU Regulatory Update:**

The EMA review of the Viaskin Peanut Marketing Authorization Application is progressing according to established EMA processes and ongoing conversations with the EMA. DBV is preparing its responses to the Day 180 letter and evaluating how to best address the Objections, including the remaining Major Objection which questions the limitations of the data, for example, the clinical relevance and effect size supported by a single pivotal study. Further exchanges with EMA are anticipated. DBV estimates the EMA could issue its decision on potential marketing authorization for Viaskin Peanut in 1Q 2022.



### Financial Highlights for the Third Quarter Ended September 30, 20211

### Cash and Cash Equivalents:

	Three months ended											
	March 31, 2020 <sup>2</sup>		June 30, 2020		September 30, 2020		December 31, 2020		March 31, 2021	June 30, 2021		September 30, 2021
		(in millions)										
Net (decrease) / increase in cash and cash equivalents, of which	\$ 94.2	\$	(34.5)	\$	(31.5)	\$	(25.1)	\$	(43.9)	\$ (27.0)	\$	(27.3)
Net cash flow used in operating activities <sup>3</sup>	(49.7)		(40.2)		(42.2)		(33.5)		(36.2)	(30.3)		(22.9)
Net cash flow provided by / (used in) investing and financial activities	149.7		(0.5)		(1.8)		(0.7)		0.3	0.8		(7.7)
Effect of exchange rate changes on cash and cash equivalents	(5.8)		6.1		12.5		9.2		(7.9)	2.5		(3.2)
Net cash and cash equivalents at the end of the period	\$ 287.4	\$	252.9	\$	221.4	\$	196.4	\$	152.5	\$ 125.5	\$	98.2

As of September 30, 2021, cash and cash equivalents were \$98.2 million, compared to \$196.4 million as of December 31, 2020 and \$125.5 million as of June 30, 2021. The \$98.2 million decrease in cash position during the first nine months of 2021, consisting of \$43.9 million, \$27.0 million, and \$27.3 million in the first, second and third quarter of 2021, respectively, was mostly comprised of \$89.5 million of net cash used in operating activities and the effect of exchange rates on cash and cash equivalents for \$(8.6) million.

The 32% decrease in net cash used in operating activities between the first nine months of 2020 and 2021 reflects the Company's continued implementation of cost containment measures and the decrease in personnel expenses related to the workforce reduction as part of the Company's global restructuring plan. Based on its current assumptions, DBV expects that its current cash and cash equivalents will support its operations into the third quarter 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 \$1.3 million and \$2.8 million,

<sup>&</sup>lt;sup>1</sup>The Company's unaudited consolidated financial statements for the quarter ended September 30, 2021 are prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").

<sup>&</sup>lt;sup>2</sup> For the three months ended March 31, 2020, net cash provided by financing activities includes \$151.0 million cash flows received in connection with DBV's follow-on public offering of its securities in the first quarter of 2020.

<sup>&</sup>lt;sup>3</sup> Net cash flows used in operating activities include restructuring amounts paid as part of the global restructuring plan launched in June 2020.



for the three and nine months ended September 30, 2021, respectively, compared to \$4.2 million and \$12.5 million for the three and nine months ended September 30, 2020, respectively. The decrease in operating 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 delays in new patient enrollment.

### Operating expenses:

	U.S. GAAP <sup>4</sup>							
	Three mont Septem			nths ended nber 30,				
(\$ in thousands)	2021	2020	2021	2020				
Operating expenses:								
Research and development	\$ (16,320)	(25,751) \$	(58,663)	(75,214)				
Sales & marketing	(1,072)	(1,595)	(2,999)	(8,114)				
General & administrative	(8,299)	(6,863)	(26,250)	(26,838)				
Restructuring	-	286	-	(21,003)				
Total Operating expenses	\$ (25,691)	(33,923) \$	(87,912)	(131,169)				

Operating Expenses for the three months ended September 30, 2021, were \$(25.7) million, compared to \$(33.9) million for the three months ended September 30, 2020. For the nine months ended September 30, 2021, operating expenses were \$(87.9) million, compared to \$(131.2) million for the nine months ended September 30, 2020, or a decrease of 33%. 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 restructuring and share-based payments expenses, employee-related costs decreased by \$13.8 million, from \$32.9 million for the nine months ended September 30, 2020 to \$19.1 million for the nine months ended September 30, 2021, a 42% decrease, compared to a 64% decrease of the average number of headcounts between the two periods (105 and 291 full-time equivalent employees for the nine months ended September 30, 2021 and 2020 respectively). As of September 30, 2021, DBV had 92 employees.

<sup>&</sup>lt;sup>4</sup>The Company's unaudited consolidated financial statements for the quarter ended September 30, 2021 are prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").



### Net Loss and Net Loss Per Share:

	U.S. GAAP <sup>5</sup>						
	Three months ended September 30,					nths ended mber 30,	
		2021	2020		2021	2020	
Net (loss) (\$ in thousands)	\$	(24,033)	(30,955)	\$	(84,136)	(120,071)	
Basic / diluted net loss per share (\$/share)	\$	(0.44)	(0.56)	\$	(1.53)	(2.23)	

For the three and nine months ended September 30, 2021, net loss was \$(24.0) million and \$(84.1) million, respectively, compared to a net loss of \$(31.0) million and \$(120.1) million, respectively, for the comparable periods in 2020.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) was \$(0.44) and \$(1.53) for the three and nine months ended September 30, 2021, respectively.

#### Conference Call Information:

DBV will host a conference call and live audio webcast on Tuesday, October 26, 2021, at 5:00 p.m. ET to report third quarter 2021 financial results and provide a corporate update.

This call is accessible via the below teleconferencing numbers, followed by the reference ID: 50247411

• United States: 1 (866) 939-3921

• Canada: 1 (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: <a href="https://www.dbv-technologies.com/investor-relations/">https://www.dbv-technologies.com/investor-relations/</a>. A replay of the presentation will also be available on DBV's website after the event.

<sup>&</sup>lt;sup>5</sup>The Company's unaudited consolidated financial statements for the quarter ended September 30, 2021 are prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").



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

	September 30, 2021			December 31, 2020		
<b>Assets</b> of which cash and cash equivalents	\$	<b>170,924</b> 98,195	\$	<b>272,246</b> 196,352		
Liabilities	\$	54,033	\$	66,754		
<b>Shareholders' equity</b> of which net result	\$	<b>116,892</b> (84,136)	\$	<b>205,491</b> (159,555)		

### CONDENSED STATEMENT OF CONSOLIDATED OPERATIONS AND COMPREHENSIVE LOSS (unaudited)

(\$ in thousands, except per share data)

		Three mon Septem 2021			nths ended mber 30, 2020
Revenue	\$	1,323 \$	4,158	\$ 2,776	\$ 12,488
Operating expenses:					
Research and development		(16,320)	(25,751)	(58,663)	(75,214)
Sales & marketing		(1,072)	(1,595)	(2,999)	(8,114)
General & administrative		(8,299)	(6,863)	(26,250)	(26,838)
Restructuring		-	286	-	(21,003)
Total Operating expenses	_	(25,691)	(33,923)	(87,912)	(131,169)
Financial Income (Expenses)	_	336	(1,184)	597	(1,380)
Income tax		-	(7)	404	(10)
Net (loss)	\$	(24,033) \$	(30,955)	\$ (84,136)	\$ (120,071)
Basic/diluted Net loss per share attributable to shareholders	\$	(0.44) \$	(0.56)	\$ (1.53)	\$ (2.23)



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

	Nine months ended September 30,				
		2021	2020		
Net cash flow used in operating activities	\$	(89,452)	\$ (132,076	5)	
Net cash flows provided by (used in) investing activities		41	(2,232	<u>'</u> )	
Net cash flows provided by (used in) financing activities		(103)	149,624	4	
Effect of exchange rate changes on cash and cash equivalents		(8,643)	12,834	4	
Net (decrease) / increase in cash and cash equivalents		(98,157)	28,150	<b>D</b>	
Net cash and cash equivalents at the beginning of the period		196,352	193,255	5	
Net cash and cash equivalents at the end of the period	\$	98,195	\$ 221,404	4	

### 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 planned regulatory and clinical efforts including timing and results of communications with regulatory agencies, and the ability of any of DBV's product candidates, if approved, to improve the lives of patients with food allergies. 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.

### **Investor Contact**

Anne Pollak
DBV Technologies
+1 857-529-2363
anne.pollak@dbv-technologies.com

### Media Contact

Angela Marcucci
DBV Technologies
+1 646-842-2393
angela.marcucci@dbv-technologies.com