

## **DBV Technologies Provides Updates on the Viaskin Peanut Program in Children and Toddlers and Reports Second Quarter and Half-Year 2024 Financial Results**

- **VITESSE enrollment in peanut allergic 4-7-year-olds is on-track and recruitment is expected to be complete by end of Q3 2024**
- **DBV submitted a labeling proposal, informed by the EPITOPE efficacy data, to the Food and Drug Administration (FDA) to address the FDA's protocol queries regarding patch wear-time in COMFORT Toddlers**
- **DBV closes Q2 2024 with a cash balance of \$66.2 million; due to cost-saving measures, the Company's cash runway is extended into Q1 2025**

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today shared an update on the Phase 3 study, VITESSE (Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy), using the modified Viaskin Peanut Patch, in children ages 4 – 7 years old with peanut allergy. The Company also provided a status update on the COMFORT (Characterization of the Optimal Management of FOOD allergy Relief and Treatment) Toddlers supplemental safety study in 1 – 3-year-olds with peanut allergy. DBV reported financial results for the second quarter and the first half of 2024. The quarterly and half-year financial statements were approved by the Board of Directors on July 30, 2024.

### **Business Update**

#### **VITESSE**

DBV Technologies reports that enrollment for the VITESSE Phase 3 pivotal study in children 4 - 7-year-olds with a peanut allergy continues to be on track to screen the last subject by the end of Q3 2024. VITESSE is a trial evaluating efficacy and safety of the modified Viaskin® Peanut patch in approximately 600 subjects (randomized 2:1) with 86 participating sites in US, Canada, Europe, UK and Australia.

*"We are pleased that sites in the U.S., Canada, Europe, Australia, and the UK are working hard to continue screening and enrolling subjects so that we are on-track to reach our goal of last subject into VITESSE by the end of Q3 2024," said Pharis*



**Mohideen, M.D. Chief Medical Officer at DBV Technologies.** *"We are seeing great momentum via our engagements at medical conferences and through our outreach efforts via the patient advocacy community and with study investigators. I look forward to the completion of study recruitment in the months to come."*

### COMFORT Toddlers

DBV Technologies and the FDA have been engaged in ongoing dialogue since May 2023 on the COMFORT Toddlers supplemental safety study in 1 – 3-year-olds with a peanut allergy. The study protocol was submitted on November 9, 2023, with comments provided by FDA on March 11, 2024. Since March, much of the dialogue between DBV and FDA regarding the COMFORT Toddlers supplemental study has focused on patch wear-time experience, including how prescribers would advise parents and caregivers to manage day-to-day variability in patch wear time.

In this context, DBV proposed an approach, informed by the EPITOPE efficacy data, that focuses on the user experience during the first 90-days of treatment. DBV submitted to the FDA draft labeling for Section 2 – Dosing and Administration, for a potential Viaskin Peanut Prescribing Information (PI), along with comprehensive supportive data and analyses. Within the first 90-days of treatment (excluding the lead-in dosing period) it is possible to identify those patients who are very likely to have a robust clinical efficacy response based on patch wear time experience (i.e., "Label-in" patients). The proposed PI recommends continuation of treatment for these patients. With the same 90-day approach, patients less likely to have a robust clinical efficacy response, identified by their patch wear-time experience, would be identified as "Label-out" patients. In these instances, the PI would recommend a shared decision-making process, between the health care provider and the parent or caregiver, to determine whether treatment should be discontinued.

Importantly, the data shows that the "Label-in" and "Label-out" populations have similar immunological characteristics at baseline and have a similar safety profile while on treatment. However, there is clearly a difference in immune physiology (i.e., local application site sensitivity to the allergen, peanut protein) which impacts an individual patient's wear time experience.

*"DBV is and always has been dedicated to families in the food allergy community—our future patients are our top priority,"* said **Daniel Tasse, Chief Executive Officer of DBV Technologies.** *"We have offered a robust proposal to the FDA with the goal of expediting and finalizing a path forward for Viaskin Peanut in 1–3-year-olds. We*



*believe the proposed labeling solution, which identifies patients to label-in and label-out of treatment with the Viaskin Peanut patch, will provide data-driven instructions to prescribers, and thus optimize Viaskin Peanut treatment for toddlers suffering from peanut allergy.*

*“On April 29<sup>th</sup>, the FDA Office of Vaccine Research and Review stated that non-COVID related backlogs were behind them, that the Division was caught-up, allowing more time for interactions with sponsors. We have indeed seen more engagement from FDA, particularly on CMC and our clinical program. DBV looks forward to continued dialogue with FDA in advancing a regulatory pathway for Viaskin Peanut in 1–3-year-olds.”*

DBV is currently awaiting FDA's response to the proposed labeling approach which was submitted on June 28<sup>th</sup>.

## **Conference Call**

DBV will host a conference call and live audio webcast on Tuesday, July 30<sup>th</sup>, at 5:30 p.m. ET to review its second quarter 2024 financial results and provide a business update.

Participants may access this call via the below teleconferencing numbers and asking to join the DBV Technologies call:

United States: +1-877-346-6112  
International: +1-848-280-6350

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.

## **Financial Highlights for the second quarter Ended June 30, 2024**

The Company's interim condensed consolidated financial statements for the six months ended June 30, 2024, are prepared in accordance with accounting principles in the U.S. ("U.S. GAAP").



## Cash and Cash Equivalents

<i>In millions of USD (unaudited)</i>	U.S. GAAP		IFRS	
	six months ended		six months ended	
	June 30,		June 30,	
	2024	2023	2024	2023
<b>Net cash &amp; cash equivalents at the beginning of the period</b>	<b>141.4</b>	<b>209.2</b>	<b>141.4</b>	<b>209.2</b>
Net cash flow used in operating activities	(69.8)	(46.4)	(68.7)	(45.4)
Net cash flow provided by / (used in) investing activities	(1.4)	(0.3)	(1.4)	(0.3)
Net cash flow provided by / (used in) financing activities	(0.1)	7.8	(1.2)	6.8
Effect of exchange rate changes on cash & cash equivalents	(3.9)	3.7	(3.9)	3.7
<b>Net cash &amp; cash equivalents at the end of the period</b>	<b>66.2</b>	<b>174.0</b>	<b>66.2</b>	<b>174.0</b>

Cash and cash equivalents amounted to \$66.2 million as of June 30, 2024, compared to \$141.4 million as of December 31, 2023, a net decrease by \$75.2 million including \$69.8 million of net cash flow used in operating activities, mainly external clinical-related expenses notably progress on patient enrollment in the VITESSE Phase 3 clinical trial.

The Company has incurred operating losses and negative cash flows from operations since inception. As of July 30<sup>th</sup>, DBV's available cash and cash equivalents are not projected to be sufficient to support the Company's operating plan for at least the next 12 months. As such, there is substantial doubt regarding its ability to continue as a going concern.

Based on its current operations, plans and assumptions, the Company expects that its balance of cash and cash equivalents will be sufficient to fund its operations into Q1 2025 due to the implementation of cost-savings measures.



The Company intends to seek additional capital as it continues research and development efforts and prepares for the launch of Viaskin Peanut, if approved.

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, including as a result of disruptions to the global financial markets due to any future pandemics, epidemics or global health crises and conflict in Ukraine or other global political or military crises. 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 or on acceptable terms, if at all.

If the Company is not successful in its financing objectives, the Company could have to scale back its operations, notably by delaying or reducing the scope of its research and development efforts or obtain financing through arrangements with collaborators or others that may require the Company to relinquish rights to its product candidates that the Company might otherwise seek to develop or commercialize independently.

This interim condensed financial information does not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company was unable to continue as a going concern.

## Operating Income

<i>In millions of USD (unaudited)</i>	U.S. GAAP		U.S. GAAP		IFRS	
	six months ended June 30,		three months ended June 30,		six months ended June 30,	
	2024	2023	2024	2023	2024	2023
Research tax credits	2.6	3.7	1.2	2.0	2.6	3.7
Other operating income	—	0.7	—	0.3	—	0.8
<b>Operating income</b>	<b>2.6</b>	<b>4.5</b>	<b>1.2</b>	<b>2.3</b>	<b>2.6</b>	<b>4.5</b>

Operating income amounted to \$2.6 million for the 6 months ended June 30, 2024, compared with \$4.5 million for the same period in 2023. This decrease by \$1.9 million is mostly due to a lower Research Tax credit entitlement as a greater proportion of studies activities are carried out in North America.



## Operating Expenses

<i>In millions of USD (unaudited)</i>	U.S. GAAP		U.S. GAAP		IFRS	
	six months ended		three months ended		six months ended	
	June 30,		June 30,		June 30,	
	2024	2023	2024	2023	2024	2023
Research & Development	(46.8)	(33.7)	(25.4)	(17.6)	(46.7)	(33.6)
Sales & Marketing	(1.7)	(0.9)	(1.0)	(0.5)	(1.7)	(0.9)
General & Administrative	(16.4)	(16.1)	(8.6)	(9.2)	(16.5)	(16.2)
<b>Operating expenses</b>	<b>(65.0)</b>	<b>(50.7)</b>	<b>(35.0)</b>	<b>(27.4)</b>	<b>(64.9)</b>	<b>(50.7)</b>

Operating expenses amounted to \$65.0 million for the six months ended June 30, 2024, compared with \$50.7 million for the six months ended June 30, 2023, an increase by \$14.3 million driven primarily by Research & Development resulting from both patient enrollment in VITESSE Phase 3 clinical trial and preparatory activities for the COMFORT studies in anticipation of initiation after FDA alignment.

Employee-related costs increased overall by \$3.1 million for the six months ended June 30, 2024, compared to the six months ended June 30, 2023, as the Company expanded headcount by 24 to support clinical, regulatory and quality activities in preparation for BLA submission.

General and Administrative expenses increased slightly during the six months ended June 30, 2024, compared to the six months ended June 30, 2023, due to the optimization and rationalization of external professional services.



## Net Loss and Net Loss Per Share

	U.S. GAAP		U.S. GAAP		IFRS	
	six months ended		three months ended		six months ended	
	June 30,		June 30,		June 30,	
	2024	2023	2024	2023	2024	2023
Net income / (loss) (in millions of USD)	(60.5)	(44.8)	(33.1)	(24.2)	(60.6)	(44.9)
Basic / diluted net income / (loss) per share (USD/share)	(0.63)	(0.48)	(0.34)	(0.26)	(0.63)	(0.48)

The Company recorded a net loss for the first six months ended June 30, 2024, of \$60.5 million, compared to a net loss of \$44.8 million for the first six months ended June 30, 2023.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) was \$(0.63) for the first six months ended June 30, 2024.

## CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (unaudited)

In millions of USD	U.S. GAAP		IFRS	
	June 30, 2024	December 31, 2023	June 30, 2024	December 31, 2023
Assets	114.2	183.0	114.2	183.0
of which cash & cash equivalents	66.2	141.4	66.2	141.4
<b>Liabilities</b>	35.1	42.8	35.0	42.7
<b>Shareholders' equity</b>	79.1	140.2	79.2	140.3



## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS(unaudited)

	U.S. GAAP		U.S. GAAP		IFRS	
	six months ended		three months		six months ended	
	June 30,		ended June 30,		June 30,	
<i>In millions of USD</i>	2024	2023	2024	2023	2024	2023
<b>Revenues</b>	<b>2.6</b>	<b>4.5</b>	<b>1.2</b>	<b>2.3</b>	<b>2.6</b>	<b>4.5</b>
Research & Development	(46.8)	(33.7)	(25.4)	(17.6)	(46.7)	(33.6)
Sales & Marketing	(1.7)	(0.9)	(1.0)	(0.5)	(1.7)	(0.9)
General & Administrative	(16.4)	(16.1)	(8.6)	(9.2)	(16.5)	(16.2)
<b>Operating expenses</b>	<b>(65.0)</b>	<b>(50.7)</b>	<b>(35.0)</b>	<b>(27.4)</b>	<b>(64.9)</b>	<b>(50.7)</b>
Financial income/(expenses)	2.0	1.5	0.7	0.8	1.8	1.4
Income tax	—	—	—	—	—	—
<b>Net loss</b>	<b>(60.5)</b>	<b>(44.8)</b>	<b>(33.1)</b>	<b>(24.2)</b>	<b>(60.6)</b>	<b>(44.9)</b>
Basic/diluted net loss per share attributable	(0.63)	(0.48)	(0.34)	(0.26)	(0.63)	(0.48)

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	U.S. GAAP		IFRS	
	six months ended		six months ended	
	June 30,		June 30,	
<i>In millions of USD</i>	2024	2023	2024	2023
Net cash flows provided / (used) in operating activities	(69.8)	(46.4)	(68.7)	(45.4)
Net cash flows provided / (used) in investing activities	(1.4)	(0.3)	(1.4)	(0.3)
Net cash flows provided / (used) in financing activities	(0.1)	7.8	(1.2)	6.8





Effect of exchange rate changes on cash & cash equivalents (U.S. GAAP presentation)	(3.9)	3.7	(3.9)	3.7
<b>Net increase / (decrease) in cash &amp; cash equivalents</b>	<b>(75.2)</b>	<b>(35.2)</b>	<b>(71.3)</b>	<b>(38.9)</b>
Net cash & cash equivalents at the beginning of the period	141.4	209.2	141.4	209.2
<b>Net cash &amp; cash equivalents at the end of the period</b>	<b>66.2</b>	<b>174.0</b>	<b>66.2</b>	<b>174.0</b>

### About DBV Technologies

DBV Technologies is a clinical-stage biopharmaceutical company developing treatment options for food allergies and other immunologic conditions with significant unmet medical need. DBV is currently focused on investigating the use of its proprietary technology platform, Viaskin, to address food allergies, which are caused by a hypersensitive immune reaction and characterized by a range of symptoms varying in severity from mild to life-threatening anaphylaxis. Millions of people live with food allergies, including young children. Through epicutaneous immunotherapy (EPIT™), the Viaskin platform is designed to introduce microgram amounts of a biologically active compound to the immune system through intact skin. EPIT is a new class of non-invasive treatment that seeks to modify an individual's underlying allergy by re-educating the immune system to become desensitized to allergen by leveraging the skin's immune tolerizing properties. DBV is committed to transforming the care of food allergic people. The Company's food allergy programs include ongoing clinical trials of Viaskin Peanut in peanut allergic toddlers (1 through 3 years of age) and children (4 through 7 years of age).

DBV Technologies is headquartered in Châtillon, France, with North American operations in Warren, NJ. The Company's ordinary shares are traded on segment B of Euronext Paris (Ticker: DBV, ISIN code: FR0010417345) and the Company's ADSs (each representing one ordinary share) are traded on the Nasdaq Capital Select Market (Ticker: DBVT).

For more information, please visit [www.dbv-technologies.com](http://www.dbv-technologies.com) and engage with us on [X \(formerly Twitter\)](#) and [LinkedIn](#).

### Forward Looking Statements

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



potential of Viaskin® Peanut patch and EPIT™, designs of DBV's anticipated clinical trials, 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. 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, 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, 2023, filed with the SEC on March 7, 2024, 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.

Viaskin is a registered trademark and EPIT is a trademark of DBV Technologies.

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