



DBV Technologies Reports Full Year 2023 Financial Results and Business Update

- Advanced Viaskin™ Peanut clinical development programs in peanut-allergic toddlers (1 through 3 years old) and children (4 through 7 years old)
- Strengthened executive leadership team in preparation for BLA submission
- Reported cash and cash equivalents of \$141 million

DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company focused on treatment options for food allergies and other immunologic conditions with significant unmet medical need, today reported financial results for the full year 2023. The audit procedures have been substantially completed by the Company's statutory auditors and financials – prepared under both US GAAP and IFRS for the purpose of Form 10-K and Universal Registration Document respectively – were approved by the Board of Directors on March 7, 2024.

“During 2023, we made significant progress advancing our two Viaskin Peanut clinical development programs in two distinct age groups, one for toddlers ages 1 to 3 years, and one for children ages 4 to 7 years,” said Daniel Tassé, Chief Executive Officer of DBV Technologies. “In 2024, we are focused on completing enrollment in VITESSE, our Phase 3 efficacy and safety trial in children. Despite the delays experienced as a result of the new European Commission directive on Clinical Trials Regulation, all countries are open and actively recruiting. We expect good momentum regarding Vitesse recruitment in the next several months and last subject screened by Q3 2024.

In addition, we are initiating two supplemental six-month safety trials, COMFORT Toddlers and COMFORT Children, as the final clinical pieces to support two separate and robust packages for our Biologics License Applications to the FDA.”

Mr. Tassé continued, “We are committed to working as swiftly and diligently as possible to bring this novel treatment option to market for toddlers and children and their families who are living with the daily and significant burden of a peanut allergy.”

2023 Operational Highlights



- Confirmed EPITOPE, DBV's Phase 3 efficacy and safety study of Viaskin Peanut in peanut-allergic toddlers aged 1 through 3 years, is sufficient for the clinical portion of a BLA, and no additional efficacy studies were requested by the FDA.
- Prepared for initiation of COMFORT Toddlers and COMFORT Children, including protocol development for both supplemental six-month safety studies.
 - Number of participants on active treatment will total approximately 600 children in each of the two BLAs, 1 to 3-year-olds and 4 to 7-year-olds.
- Implemented simplified protocol language for both COMFORT Toddlers and COMFORT Children indicating that Viaskin Peanut is "intended to be worn for a full day" with any reference to minimum wear time removed.
- Initiated VITESSE, a Phase 3 clinical trial to evaluate the efficacy and safety of the circular Viaskin Peanut patch in peanut-allergic children aged 4 through 7 years and activated more than 85 trial sites across North America, Australia and Europe.
- [Published EPITOPE results](#) in the New England Journal of Medicine with an accompanying editorial, entitled, *Good News for Toddlers with Peanut Allergy*.
- [Presented interim safety and efficacy data from the open-label extension of EPITOPE](#), which demonstrate a robust continued treatment effect with Viaskin Peanut after two years of treatment, at The American College of Allergy, Asthma, and Immunology annual meeting.
- Strengthened the executive leadership team with the appointment of Virginie Boucinha as Chief Financial Officer and Dr. Kevin Malobisky, PhD., as Chief Operations Officer.

Anticipated 2024 Events

- Initiate COMFORT Toddlers, the six-month supplemental safety trial in support of BLA.
- Screen last patient in VITESSE, now expected by Q3 2024.
- Initiate COMFORT Children, the six-month supplemental safety trial in support of BLA.
- Announce top-line efficacy and safety data from year three of EPITOPE, corresponding to end-of-study results for participants completing three years of active treatment.
- Publish manuscripts including invited reviews in peer-reviewed scientific journals and submit abstracts on new data at upcoming scientific conferences.

Financial Highlights for the Full Year 2023



2023 Financial Highlights are presented under both U.S GAAP and IFRS. Financial statements comments refer to U.S. GAAP financial statements.

Differences between US GAAP and IFRS consolidated financial statements result mainly from the discrepancies arising from the application of lease accounting standards.

Cash and cash equivalents totaled \$141.4 million as of December 31, 2023, compared to \$209.2 million as of December 31, 2022, a net decrease of \$67.8 million.

- Overall, the Company used \$79.6 million of cash in operations, primarily in Research and Development, with the initiation of the VITESSE trial, with the first patient screened in March 2023, preparation activities related to COMFORT studies, as well as an increase in regulatory and pre-commercialization activities. Cash used in operations increased by \$23.9 million as of December 2023 compared to December 2022.
- Cash provided by financing activities decreased by \$187.4 million in 2023, compared to 2022. In June of 2022, the Company had completed a private placement financing (“PIPE”) which raised total net proceeds of \$194.4 million. The net proceeds from the issuance and sale of new ordinary shares in the form of American Depositary Shares (“ADSs”) on June 16, 2023, totaled \$6.9 million.
- The Company also benefitted from a favorable exchange rate in the amount of \$5.9 million.

Operating income amounts to \$15.7 million as of December 31, 2023, an increase of \$10.9 million compared to \$4.8. million as of December 31, 2022, mainly due to:

- A \$7.8 million increase in other operating income from revenues recognized as part of the Development, Collaboration, and Licensing Agreement with Nestlé Health Science (the “Nestlé Collaboration Agreement”), which terminated on October 30th, 2023.



- Research Tax Credit increase by \$3.0 million. As of December 31, 2023, the Company filed an additional research tax credit claim for the years 2020, 2021 and 2022.

Operating income, excluding revenues from the Nestlé, Collaboration, Agreement amounts to \$8.8 million.

Operating expenses amount to \$92.2 million as of December 31, 2023, compared to \$101.5 million as of December 31, 2022, a decrease of \$9.3 million due to:

- (1) A \$15.3 million decrease in Research and Development expenses, composed of:
 - a. A \$30.7 million favorable impact due to the termination of Nestlé Collaboration Agreement (primarily the reversal of the loss on completion accrual by \$17.6 million in 2023 compared to a \$10.4 million loss on completion accrual as of December 31st, 2022).
 - b. An increase of \$15.4 million in Research and Development expenses reflecting intensified Research and Development activities following the initiation of the VITESSE trial, with the first patient screened in March 2023, as well as preparations for COMFORT.
- (2) A \$5.2million increase in General and Administrative expenses, primarily due to \$2.8 million in external services fees incurred in the Company's financing activities.
- (3) A \$0.8 million increase in Sales and Marketing expenses related to pre-commercialization activities for Viaskin Peanut in North America.

Operating expenses totaled \$107.3 million as of December 31, 2023, when excluding the loss on completion accrual reversal from the Nestlé Collaboration Agreement.

DBV recorded a net loss of \$72.7 million as of December 31, 2023, compared to a net loss of \$96.3 million as of December 31, 2022.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) is \$0.76 as of December 31, 2023.



Excluding the Nestlé Collaboration Agreement termination, net loss as of December 31, 2023, would amount to \$94.7 million.

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

Based on current operations, as well as plans and assumptions, the Company expects that its balance of cash and cash equivalents of \$141,4 million as of December 31, 2023, will be sufficient to fund its operations until December 31, 2024. The Company intends to seek additional capital through debt and equity offerings as it continues research and development efforts and prepares for the launch of Viaskin Peanut, if approved.

Conference Call Information

DBV will host a live conference call and webcast today at 5:00 p.m. ET to discuss full year 2023 financial results and provide a business update. The conference call may be accessed by dialing:

- United States: 1-844-481-2866
- International: 1-412-317-1859

A webcast of the call will also be available under "Events" in the Investors section of the DBV Technologies website: <https://dbv-technologies.com/investor-overview/events>. A replay of the presentation will also be available on DBV's website after the event.

Cash and Cash Equivalents

In millions of USD	US GAAP		IFRS	
	Year ended December 31, 2023	2022	Year ended December 31, 2023	2022
Net cash & cash equivalents at the beginning of the period	209,2	77,3	209,2	77,3
Net increase/(decrease) in cash & cash equivalents, of which:	(67,8)	131,9	(67,8)	131,9

Net cash flow used in operating activities	(79,6)	(55,7)	(77,6)	(51,4)
Net cash flow used in investing activities	(0,8)	(0,1)	(0,8)	(0,1)
Net cash flow provided by / ((used in) financing activities	6,7	194,1	4,8	189,9
Effect of exchange rate changes on cash & cash equivalents	5,9	(6,5)	5,8	(6,5)
Net cash & cash equivalents at the end of the period	141,4	209,2	141,2	209,2

Operating income

In millions of USD	US GAAP				IFRS			
	Year ended December 31,				Year ended December 31,			
	2023	2022	Variation		2023	2022	Variation	
Research tax credit	8,8	5,7	+3,0	+53%	8,8	5,7	+3,0	+53%
Other operating income	6,9	(0,9)	+7,8	-896%	6,9	(0,9)	+7,8	-896%
Operating income	15,7	4,8	+10,9	+225%	15,7	4,8	+10,9	+225%

Operating expenses

In millions of USD	US GAAP				IFRS			
	Year ended December 31,				Year ended December 31,			
	2023	2022	Variation		2023	2022	Variation	
Research & Development	60,2	75,5	-15,3	-20%	60,1	75,2	-15,1	-20%
Sales & Marketing	2,4	1,6	+0,8	+52%	2,4	1,6	+0,8	+56%
General & Administrative	29,5	24,3	+5,2	+21%	29,5	24,2	+5,2	+22%
Total operating expenses	92,2	101,5	-9,3	-9%	92,0	101,0	-9,0	-9%
<i>including internal compensation</i>	29,2	24,0	+5,2	+22%	29,3	24,0	+5,3	+22%

Net Loss and Net Loss per Share



	US GAAP				IFRS			
	Year ended December 31,				Year ended December 31,			
	2023	2022	Variation		2023	2022	Variation	
Net (loss) in millions of USD	(72,7)	(96,3)	+23,5	-24%	(72,7)	(96,0)	+23,1	-24%
Basic / diluted net (loss) per share in USD	(0,76)	(1,24)	+0,5	-38%	(0,76)	(1,24)	+0,5	-38%

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 Montrouge, France, with North American operations in Basking Ridge, 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-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

For more information, please visit www.dbvtechnologies.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 forecast of its cash runway, the therapeutic potential of Viaskin™ Peanut 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, 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, 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.

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