

DBV Technologies Reports First Quarter 2024 Financial Results and Business Update

- VITESSE enrollment on track to screen last patient by Q3 2024
- Appointment of Robert Pietrusko, PharmD to Chief Regulatory Officer
- Q1 2024 closes with a cash balance of \$101.5 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 first quarter 2024. The quarterly financial statements were approved by the Board of Directors on May 7, 2024.

Recent Business Developments

Clinical and Regulatory Update

Enrollment for VITESSE, DBV's Phase 3 pivotal study of the modified Viaskin Peanut patch in children ages 4 through 7 years with peanut allergy passed the halfway point for recruitment in Q1 and continues to be on track to screen the last patient by Q3 2024. VITESSE is a trial evaluating efficacy and safety in approximately 600 subjects (randomized 2:1) with 86 participating sites in US, Canada, Europe, UK and Australia.

"We are pleased with VITESSE enrollment rates and thrilled that our sites in Europe and the UK are actively enrolling subjects and have increased the momentum for VITESSE," said **Pharis Mohideen, M.D. Chief Medical Officer at DBV Technologies.** *"This comes on the heels of the February AAAAI meeting where there was tremendous interest in Viaskin Peanut and standing room only, record breaking attendance at our product theatre "Importance of Early Intervention for Peanut Allergy."*

The Company submitted the protocol for its COMFORT Toddlers supplemental safety study in 1 through 3-year-olds to the FDA on November 9, 2023. The Company and the FDA are engaged in ongoing dialogue related to the program.

Appointment of Robert Pietrusko, Chief Regulatory Officer

DBV has strengthened its regulatory expertise by appointing Robert Pietrusko, PharmD, to the position of Chief Regulatory Officer. Bob brings a wealth of expertise



to DBV through his more than four decades of biopharmaceutical regulatory experience.

Bob joins DBV from Vor Bio, where he has served as Chief Regulatory Officer since April 2020. He previously served as Senior Vice President of Regulatory Affairs & Quality Assurance at Voyager Therapeutics, Inc., and as Vice President of Global Regulatory Affairs and Quality at ViroPharma Incorporated (acquired by Shire in 2013). He has served in regulatory and quality assurance roles of increasing responsibility at Millennium Pharmaceuticals (acquired by Takeda in 2008) and SmithKline Beecham (part of GlaxoSmithKline).

Bob has led the regulatory effort leading to more than 35 BLA/NDA/MAA approvals globally including in the US across many FDA Divisions at both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). He is also a leader in regulatory policy through his involvement as Chair of the Regulatory Affairs Committee of the Alliance for Regenerative Medicine (ARM) and an appointed member of the Regulatory Affairs committee of the American Society of Gene and Cell Therapies (ASGCT).

"Bob brings to DBV extensive regulatory affairs and quality expertise, and his leadership is an important addition to the company," stated Daniel Tassé, Chief Executive Officer of DBV Technologies. "In addition to his deep understanding of complex development programs, he has a proven track record of shepherding multiple products through the regulatory process to approval across the various divisions of the FDA. Bob's guidance will be instrumental as we continue the development of Viaskin Peanut in toddlers and children. We are thrilled to welcome him to our team."

Financial Highlights for the First Quarter Ended March 31, 2024

The Company's interim condensed consolidated financial statements for the three months ended March 31, 2024, are prepared in accordance with accounting principles in the U.S. ("U.S. GAAP").

Cash and Cash Equivalents

In millions of USD (unaudited)	U.S. GAAP
	three months ended March 31



	2024	2023
Net cash & cash equivalents at the beginning of the period	141,4	209,2
Net cash flow used in operating activities	(34,7)	(20,8)
Net cash flow provided by / (used in) investing activities	(2,1)	-
Net cash flow provided by / (used in) financing activities	(0,1)	-
Effect of exchange rate changes on cash & cash equivalents	(3,0)	3,9
Net cash & cash equivalents at the end of the period	101,5	192,3

Cash and cash equivalents amount to \$101,5 million as of March 31, 2024, compared to \$141,4 million as of December 31, 2023, a net decrease by \$39,8 million including \$34,7 million of net cash flow used in operating activities, mainly external clinical-related expenses explained by progress on patient enrollment in VITESSE Phase 3 clinical trial.

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 our current operations, as well as our plans and assumptions, we expect that our balance of cash and cash equivalents of \$101.5 million as of March 31, 2024, will be sufficient to fund our operations until December 31, 2024. The Company intends to seek additional capital as it continues research and development efforts and prepares for the launch of Viaskin Peanut, if approved.

Operating Income

In millions of USD (unaudited)	U.S. GAAP	
	three months ended March 31	
	2024	2023

Research tax credits	1,4	1,8
Other operating income	-	0,4
Operating income	1,4	2,2

Operating income amounts to \$1,4 million for the first 3 months ended March 31, 2024, compared with \$2,2 million for the same period in 2023, a decrease by \$0,8 million mainly resulting from the contract termination with Nestlé Health Science for \$0,4 million.

Operating Expenses

In millions of USD (unaudited)	U.S. GAAP	
	three months ended March 31	
	2024	2023
Research & Development	21,4	16,0
Sales & Marketing	0,8	0,5
General & Administrative	7,8	6,9
Operating expenses	30,0	23,4

Operating expenses amount to \$30 million in the first quarter, compared with \$23,4 million at March 31, 2023, an increase of \$6,6 million mainly due to the increase in research and development activities in particular VITESSE Phase 3 clinical trial.

Net Loss and Net Loss Per Share

	U.S. GAAP	
	three months ended March 31	
	2024	2023
Net income / (loss) (in millions of USD)	(27,3)	(20,6)



Basic / diluted net income / (loss) per share (USD/share)	(0,28)	(0,22)
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Net result for the first three months ended March 31, 2024, is a loss amounting to \$27,3 million, compared to a loss amounting to \$20,6 million for the first three months ended March 31, 2023.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) is \$0,28 for the first three months ended March 31, 2024.

CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION (unaudited)

In millions of USD	U.S. GAAP	
	March 31, 2024	December 31, 2023
Assets	145,9	183,0
of which cash & cash equivalents	101,5	141,4
Liabilities	34,2	42,8
Shareholders' equity	111,7	140,2
of which net result	(27,3)	(72,7)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

In millions of USD	U.S. GAAP	
	Three months ended March 31	
	2024	2023
Revenues	1,4	2,2
Research & Development	(21,4)	(16,0)
Sales & Marketing	(0,8)	(0,5)



General & Administrative	(7,8)	(6,9)
Operating expenses	(30,0)	(23,4)
Financial income/(expenses)	1,2	0,6
Income tax	-	-
Net loss	(27,3)	(20,6)
Basic/diluted net loss per share attributable to shareholders	(0,28)	(0,22)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

In millions of USD	U.S. GAAP	
	Three months ended March 31	
	2024	2023
Net cash flows provided / (used) in operating activities	(34,7)	(20,8)
Net cash flows provided / (used) in investing activities	(2,1)	-
Net cash flows provided / (used) in financing activities	(0,1)	-
Effect of exchange rate changes on cash & cash equivalents (U.S. GAAP presentation)	(3,0)	3,9
Net increase / (decrease) in cash & cash equivalents	(39,9)	(16,9)
Net cash & cash equivalents at the beginning of the period	141,4	209,2
Net cash & cash equivalents at the end of the period	101,5	192,3

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 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-half of one ordinary share) are traded on the Nasdaq Global Select Market (Ticker: DBVT).

For more information, please visit 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 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.

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