

DBV Technologies Reports Recent Business Developments and First Quarter 2022 Financial Results

- The U.S. Food and Drug Administration (FDA) has granted DBV Technologies a Type C meeting to align on the new Viaskin Peanut Phase 3 study protocol
- The study protocol was recently submitted to the FDA as part of the Type C briefing materials

DBV Technologies S.A. (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today announced business updates concerning the regulatory status for its lead product candidate, Viaskin Peanut. The Company also reported financial results for the first quarter of 2022. The quarterly financial statements were approved by the Board of Directors on April 29, 2022.

Recent Business Developments

DBV has been granted a Type C meeting by the FDA in the second quarter to align on key design elements of the new Phase 3 study protocol, which was recently submitted to the FDA as part of the Type C briefing materials. Once DBV and the FDA have fully aligned on the Phase 3 protocol, DBV will publicly communicate the results of these discussions. DBV will continue to work with the FDA as appropriate to facilitate a timely review.

The new Phase 3 pivotal study for modified Viaskin Peanut (mVP) has been named **VITESSE** (Viaskin Peanut Immunotherapy Trial to Evaluate Safety, Simplicity and Efficacy). VITESSE, which means “speed” in French, is a nod to DBV’s French origins and belief that the launch of a new pivotal study is the fastest way to potentially bring Viaskin Peanut to patients and families in need of treatment options.

“We are pleased to have been granted a Type C meeting by the FDA and to have submitted the protocol for VITESSE, our new pivotal study for the mVP patch,” said Daniel Tassé, Chief Executive Officer, DBV Technologies. *“DBV and FDA continue to engage in productive exchanges. We are looking forward to further aligning with the FDA on the VITESSE protocol.”*

DBV is expecting top-line results of the EPITOPE (EPIT in TOddlers with PEanut Allergy) trial by the end of Q2 2022. EPITOPE is a Phase 3 trial assessing the safety and efficacy of Viaskin Peanut 250 µg for the treatment of peanut allergic toddlers 1 – 3 years old. This study was initiated shortly after starting the PEPITES study in 4-11-year-olds with peanut



allergy. The information gained from the EPITOPE study, particularly given the younger age range, should help to further our understanding of EPIT and Viaskin Peanut.

Financial Highlights for the First Quarter Ended March 31, 2022¹

DBV has continued to practice strong financial discipline. Based on current assumptions, DBV maintains that its current cash and cash equivalents will support operations into Q1 2023. This cash runway has been achieved through careful prioritization of our regulatory programs, continued budget discipline measures, and with support from the French Crédit Impôt Recherche (CIR), which is a tax credit offered by the French Government to support companies focused on Research and Development activities. DBV expects that the current cash balance will sufficiently support Company operations while alignment with the FDA on the VITESSE protocol is achieved.

Cash and Cash Equivalents

(in million)	Three months Ended	
	March 31, 2022	March 31, 2021
Net (decrease) / increase in cash and cash equivalents, of which	\$ (3.2)	\$ (43.9)
Net cash flow used in operating activities²	(1.5)	(36.2)
<i>Net cash flow provided by / (used in) investing and financial activities</i>	<i>(0.1)</i>	<i>0.3</i>
<i>Effect of exchange rate changes on cash and cash equivalents</i>	<i>(1.6)</i>	<i>(7.9)</i>
Net cash and cash equivalents at the end of the period	\$ 74.1	\$ 152.5

As of March 31, 2022, cash and cash equivalent were \$74.1 million, compared to \$77.3 million as of December 31, 2021. The \$3.2 million decrease in cash position during the first three months of 2022 was mostly comprised of a \$20.9 million cash flows received following the reimbursement of the 2019 and 2020 Research Tax Credit (French Crédit Impôt Recherche, or CIR) offset by a \$22.4 million cash utilization in operating activities and the effect of exchange rates on cash and cash equivalents for \$(1.6) million.

¹The Company's unaudited consolidated financial statements for the quarter ended March 31, 2022 are prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").

²For the three months ended March 31, 2022, net cash used in operating activities includes \$20.9 million cash flows following the reimbursement of the 2019 and 2020 Research Tax Credit (French Crédit Impôt Recherche, or CIR).



Excluding reimbursement of Research Tax Credit, the cash used in operating activities decreased by 38% between the first three months of 2021 and 2022 reflects 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 into the first quarter of 2023.

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 \$2.5 million for the three months ended March 31, 2022, respectively, compared to \$2.9 million for the three ended March 31, 2021.

Operating expenses

(in thousands \$)	Three months ended March 31,	
	2022	2021
Operating expenses :		
Research and development	\$ (12,223)	\$ (22,164)
Sales & marketing	(464)	(729)
General & administrative	(6,630)	(9,683)
Total Operating expenses	\$ (19,317)	\$ (32,575)

Operating Expenses for the three months ended March 31, 2022 were \$(19.3) million, compared to \$(32.6) million for the three months ended March 31, 2021 or -41%. DBV has continued to practice financial diligence and implemented further cost containment strategies.

Excluding share-based payments expenses, employee-related costs decreased by \$3.0 million, from \$7.6 million for the three months ended March 31, 2021 to \$4.6 million for the three months ended March 31, 2022, a 40% decrease, compared to a 27% decrease of the average number of headcounts between the two periods (88 and 121 full-time equivalent employees for the three months ended March 31, 2022 and 2021, respectively). As of March 31, 2022, DBV had 87 employees.



Net Loss and Net Loss Per Share

	U.S. GAAP	
	March 31,	
	2022	2021
Net (loss) (\$ in thousands)	\$ (16,706)	\$ (29,449)
Basic / diluted net loss per share (\$/share)	\$ (0.30)	\$ (0.54)

For the three months ended March 31, 2022, net loss was \$(16.7) compared to a net loss of \$(29.4) million for the comparable period in 2021.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) was \$(0.30) and \$(0.54) for the three months ended March 31, 2022 and 2021, respectively.

Conference Call Information

As previously announced, DBV will host a conference call and live audio webcast on Monday, May 2, 2022, at 5:00 p.m. ET to report first quarter 2022 financial results and provide a corporate update.

This call is accessible via the below teleconferencing numbers, followed by the reference ID: 89119188.

- United States: 866 374 5410
- Canada: 866 455 3403
- United Kingdom: 808 238 9813
- France: 805 102 712

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.



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

	U.S. GAAP ³	
	March 31, 2022	December 31, 2021
Assets	\$ 117,581	\$ 146,723
<i>of which cash and cash equivalents</i>	<i>74,107</i>	<i>77,301</i>
Liabilities	35,519	47,449
Shareholders' equity	\$ 82,062	\$ 99,274
<i>of which net result</i>	<i>(16,706)</i>	<i>(29,449)</i>

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

	U.S. GAAP ³	
	March 31,	
(in thousands \$)	2022	2021
Revenue	\$ 2,546	\$ 2,941
Operating expenses :		
Research and development expenses	\$ (12,223)	\$ (22,164)
Sales and marketing expenses	(464)	(729)
General and administrative expenses	(6,630)	(9,683)
Total Operating expenses	\$ (19,317)	\$ (32,575)
Financial income	152	215
Income tax	(87)	(30)
Net (loss)	\$ (16,706)	\$ (29,449)
Basic/diluted Net loss per share attributable to shareholders	\$ (0.30)	\$ (0.54)

³ Unaudited financial statements prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP").



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

	U.S. GAAP⁴	
	March 31,	
	2022	2021
Net cash flow used in operating activities	\$ (1,483)	\$ (36,204)
Net cash flows provided by (used in) investing activities	11	(185)
Net cash flows (used in) provided by financing activities	(129)	440
Effect of exchange rate changes on cash and cash equivalents	(1,594)	(7,944)
Net decrease in cash and cash equivalents	(3,194)	(43,893)
Net cash and cash equivalents at the beginning of the period	77,301	196,352
Net cash and cash equivalents at the end of the period	\$ 74,107	\$ 152,459

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 Basking Ridge, New Jersey. 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).

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



Forward Looking Statements

This press release may contain forward-looking statements and estimates, including statements regarding DBV's forecast of its cash runway, designs of DBV's anticipated clinical trials, 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, 2021, filed with the SEC on March 9, 2022, 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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