UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

March 3, 2022 Date of Report (Date of earliest event reported)

DBV Technologies S.A. (Exact name of registrant as specified in its charter)

France (State or other jurisdiction of incorporation)

001-36697 (Commission File Number)

Not applicable (IRS Employer Identification No.)

177-181 avenue Pierre Brossolette 92120 Montrouge France (Address of principal executive offices)

Not Applicable (Zip Code)

Registrant's telephone number, including area code: +33 1 55 42 78 78

| | - | | | | | | | | | |
|-----|---|--|---|--|--|--|--|--|--|--|
| | ck the appropriate box below if the Form 8-K filing is interowing provisions: | nded to simultaneously satisfy the filin | g obligation of the registrant under any of the | | | | | | | |
| | □ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) | | | | | | | | | |
| | □ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) | | | | | | | | | |
| | Pre-commencement communications pursuant to Rule 1 | 4d-2(b) under the Exchange Act (17 C | FR 240.14d-2(b)) | | | | | | | |
| | Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) | | | | | | | | | |
| Sec | urities registered pursuant to Section 12(b) of the Act: | | | | | | | | | |
| | Title of each class | Trading Symbol(s) | Name of each exchange on which registered | | | | | | | |
| Ar | rdinary shares, nominal value €0.10 per share nerican Depositary Shares, each representing me-half of one ordinary share, nominal value €0.10 per share | n/a DBVT | The Nasdaq Stock Market LLC * The Nasdaq Stock Market LLC | | | | | | | |
| * N | of for trading, but only in connection with the listing of the | ne American Depositary Shares on The | e Nasdaq Stock Market LLC. | | | | | | | |
| | cate by check mark whether the registrant is an emerging pter) or Rule 12b-2 of the Securities Exchange Act of 1934 | | 5 of the Securities Act of 1933 (§ 230.405 of this | | | | | | | |
| | | | Emerging growth company \Box | | | | | | | |
| | n emerging growth company, indicate by check mark if the evised financial accounting standards provided pursuant | 2 | 1 110 | | | | | | | |

Item 2.02. Results of Operations and Financial Condition

On March 3, 2022, DBV Technologies S.A. (the "Company") issued a press release announcing financial results and business highlights for the fiscal quarter and year ended December 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit

No. Description

99.1 Press Release issued March 3, 2022

104 Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DBV TECHNOLOGIES S.A. Date: March 3, 2022

/s/ Sébastien Robitaille

By: /s/ Sébastien Robitaille
Name: Sébastien Robitaille
Title: Chief Financial Officer



Press Release

Montrouge, France, March 3, 2022

DBV Technologies Reports Full Year 2021 Financial Results and Recent Business Updates

mVP Pivotal Protocol Complete and Ready for Submission to FDA

DBV Continues to Engage in Productive Exchanges with FDA

Cash Runway Extended into the First Quarter 2023

DBV Technologies S.A. (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage specialty biopharmaceutical company, today reported financial results for the full year of 2021. The audit procedures have been substantially completed by the Company's statutory auditors and financials were approved by the Board of Directors on March 3, 2022. The audit report will be issued by the Company's auditors in March 2022.

DBV has extended its cash runway into the first quarter of 2023 as a result of continued financial diligence and cost containment measures. These targeted efforts adequately support the critical research and development work underway to advance the Viaskin platform. The protocol for the new Phase 3 pivotal study of the modified Viaskin Peanut ("mVP") patch was completed at the end of February 2022 and has been prepared for FDA submission. The Company is currently engaged in fruitful discussions with FDA in preparation for protocol submission and review. DBV expects to complete protocol submission following further alignment with FDA.

"Initiating our new Phase 3 trial with the mVP is our top priority. We are pleased with our ongoing exchanges with FDA. In parallel to these discussions, DBV continues to maximize the efficiency of its spend. Based on our current assumptions, we have extended our cash runway into the first quarter of 2023," said Daniel Tasse, Chief Executive Officer, DBV Technologies. "We expect that this cash position, combined with our continued discipline to reduce general and administrative expenses without sacrificing research and development, will give DBV sufficient time to gain alignment with FDA on the protocol for the mVP pivotal trial. DBV has been strategic in advancing its EPIT pipeline, and through these efforts, we aim to realize the full potential of the Viaskin technology for patients and families.



Full-Year 2021 Financial Highlights 1

Cash and Cash Equivalents

| | U.S. GAAP | | | IFRS | | | | | |
|--|---------------------------|------------------|--------------|-------------------------|-------------|-------------------------|----------|-------------------------|--|
| | Year ended, | | | | Year ended, | | | | |
| | December 31, December 31, | | December 31, | | December 3 | | | | |
| (in millions) | | 2021 2020 (*) | | | | 2021 | 2020 (*) | | |
| Net (decrease) / increase in cash and cash equivalents, of which | \$ | (119.1) | \$ | 3.1 | \$ | (119.1) | \$ | 3.1 | |
| Net cash flow used in operating activities Net cash flow provided by / (used in) investing activities | | (108.2) (0.4) | | (165.6) (2.9) | | (104.1) (0.4) | | (160.9) (2.9) | |
| Net cash flow provided by / (used in) financial activities Effect of exchange rate changes on cash and cash | | 0.3 | | 1 4 9.5 | | (3.9) | | 144.8 | |
| equivalents | | (10.7) | | 22.0 | | (10.7) | | 22.0 | |
| Net cash and cash equivalents at the end of the period | \$ | 77.3 | \$ | 196.4 | \$ | 77.3 | \$ | 196.4 | |

^(*) including \$150.0 million cash flows provided by 1Q20 capital increase

As of December 31, 2021, cash and cash equivalents were \$77.3 million, compared to \$196.4 million as of December 31, 2020. In 2021, cash used in operating activities was \$(108.2) million under U.S. GAAP and \$(104.1) million under IFRS compared to \$(165.6) million under U.S. GAAP and \$(160.9) million under IFRS in 2020.

The 35% decrease in net cash used in operating activities between the years ended December 31, 2021 and 2020 reflects the Company's continued implementation of budget discipline measures.

Over the past 2 years, DBV reduced its net cash used in operating activities by 54%.

Net cash used in operating activities, including restructuring amounts paid as part of the global restructuring plan launched in June 2020 (in millions of \$)

| | % Change | | | | | | |
|---|----------|---------|-------------|---------|---------|---------|--|
| | | VS | % Change vs | | | | |
| | FY21 | FY20 | 2H21 | 1H21 | 2H20 | 1H20 | |
| Net cash flow used in operating activities - U.S.GAAP | (108.2) | (34.7)% | (41.7) | (37.3)% | (45.0)% | (53.6)% | |
| Net cash flow used in operating activities - IFRS | (104.1) | (35.3)% | (40.0) | (37.6)% | (45.4)% | (54.3)% | |

The Company's annual consolidated financial statements are prepared in accordance with both generally accepted accounting principles in the U.S. ("U.S. GAAP") and International Financial Reporting Standards ("IFRS") as adopted by the European Union. Unless otherwise indicated, the financial figures presented in the Full Year 2021 Financial Highlights comply with both U.S GAAP and IFRS financial statements. Differences between U.S. GAAP and IFRS consolidated financial statements are mainly due to discrepancies arising from the application of lease accounting standards.



Cash flows used in investment activities were \$(0.4) million in 2021, compared to \$(2.9) million in 2020.

Cash from financing activities were \$0.3 million under U.S. GAAP and \$(3.9) million under IFRS compared to net cash flows provided by financing activities of \$149.5 million under U.S. GAAP and \$144.8 million under IFRS in 2020, including \$150.0 million received in connection with DBV's follow-on public offering of its securities in the first quarter of 2020.

DBV has continued to practice financial diligence and implemented further cost containment strategies. Based on its current operations, as well as its plans and assumptions as revised pursuant to its change of strategy announced in December 2021, 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 \$5.7 million, for the year ended December 31, 2021, compared to \$11.3 million the year ended December 31, 2020. 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 recruitments' delays.

Operating Expenses

| | U.S. C | IFRS | | | |
|-------------------------------------|--------------------------|-----------|-----------|-----------|--|
| (in thousands of \$) | ands of \$) December 31, | | | | |
| | 2021 | 2020 | 2021 | 2020 | |
| Operating expenses : | | | | | |
| Research and development expenses | (70,336) | (101,607) | (70,104) | (101,346) | |
| Sales and marketing expenses | (4,387) | (9,879) | (4,403) | (9,747) | |
| General and administrative expenses | (30,520) | (35,081) | (30,385) | (35,137) | |
| Restructuring income (expenses) | 920 | (23,552) | 920 | (22,994) | |
| Total Operating expenses | (104,323) | (170,118) | (103,972) | (169,224) | |

Operating Expenses for the year ended December 31, 2021, were \$104.3 million under U.S. GAAP and \$104.0 million under IFRS, compared to \$170.1 million under U.S. GAAP and \$169.2 million under IFRS for the year ended December 31, 2020. 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 \$19.2 million, from \$42.0 million for the year ended December 31, 2020 to \$22.7 million for the year ended December 31, 2021, under U.S. GAAP. Under IFRS, excluding share-based payments expenses, employee-related costs decreased by \$19.5 million, from \$42.3 million for the year ended December 31, 2020 to \$22.8 million for the year ended December 31, 2021.

The average headcount decreased by 63% between the two periods, from 270 full-time equivalent employees for the year ended December 31, 2020 to 101 for the year ended December 31, 2021. As of December 31, 2021, DBV had 92 employees.

Net Loss and Net Loss Per Share

| | U.S | S. GAAP | IFRS | | | | | | |
|---|------------|-----------------|----------------|-----------|--|--|--|--|--|
| (\$ in thousands) | Dece | ember 31, | December 31, | | | | | | |
| | 2021 | 2020 | 2021 | 2020 | | | | | |
| Net (loss) | \$ (97,809 | 9) \$ (159,555) | \$ (98,052) \$ | (159,665) | | | | | |
| Basic / diluted net loss per share (\$/share) | \$ (1.78 | 3) \$ (2.95) | \$ (1.79) \$ | (2.95) | | | | | |

For the year ended December 31, 2021, net loss was \$(97.8) million under U.S. GAAP and \$(98.1) million under IFRS, compared to a net loss of \$(159.6) million and \$(159.7) million, respectively, for the year ended December 31, 2020.

On a per share basis, net loss (based on the weighted average number of shares outstanding over the period) was \$(1.78) under U.S. GAAP and \$(1.79) under IFRS for the year ended December 31, 2021.

Conference Call Information:

DBV will host a conference call and live audio webcast on Thursday, March 3, 2022, at 5:00 p.m. ET to report fourth quarter and full year 2021 financial results and review recent business updates.

This call is accessible via the below teleconferencing numbers, followed by the reference ID: 50283860

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: 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. GAAP2 | | | IFRS3 | | | | |
|------------------------------------|------------------|----|-----------|-------|--------------|----|-----------|--|
| | December 31, | | | | December 31, | | | |
| | 2021 2020 | | | 2021 | | | 2020 | |
| Assets | \$ 146,723 | \$ | 272,246 | \$ | 146,323 | \$ | 272,019 | |
| of which cash and cash equivalents | 77,301 | | 196,352 | | 77,301 | | 196,352 | |
| Liabilities | 47,449 | | 66,754 | | 47,294 | | 66,631 | |
| Shareholders' equity | \$ 99,274 | \$ | 205,491 | \$ | 99,030 | \$ | 205,388 | |
| of which net result | (97,809) | | (159,555) | | (98,052) | | (159,665) | |

CONDENSED STATEMENT OF CONSOLIDATED OPERATIONS AND COMPREHENSIVE LOSS (unaudited)

(\$ in thousands, except per share data)

| | U.S. GAAP2 December 31, 2021 2020 | | | December 2021 | | | 31, 2020 | |
|---|-----------------------------------|----------|-----------|------------------|----------|----------|-------------|-------------------|
| Revenue | \$ | 5,708 | \$ 11.276 | | \$ 5,708 | | \$ | 11,276 |
| Operating expenses : | | | | · | | • | | • |
| Research and development expenses | | (70,336) | (| 101,607) | | (70,104) | (1 | 101,346) |
| Sales and marketing expenses | | (4,387) | | (9,879) | | (4,403) | | (9,747) |
| General and administrative expenses | | (30,520) | | (35,081) | | (30,385) | | (35,137) |
| Restructuring income (expenses) | | 920 | | (23,552) | | 920 | | (22,994) |
| Total Operating expenses | (| 104,323) | (| 170,118) | (| 103,972) | (1 | 169,225) |
| Financial income (expenses) | | 425 | | (724) | | (169) | | (1,727) |
| Income tax | | 381 | | 10 | | 381 | | ` 10 [′] |
| Net (loss) | \$ | (97,809) | \$(| 159,555) | \$ | (98,052) | \$(1 | 159,665) |
| Basic/diluted Net loss per share attributable to shareholders | \$ | (1.78) | \$ | (2.95) | \$ | (1.79) | \$ | (2.95) |

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

Unaudited financial statements prepared in accordance with International Financial Reporting Standards ("IFFS") as adopted by the European Union. 2



CONDENSED STATEMENT OF CONSOLIDATED CASH FLOW (unaudited)

(\$ in thousands)

| | 0.5. 0 | ILL | (2) | |
|--|-------------|-------------|-------------|-------------|
| | Decem | Decem | ber 31, | |
| | 2021 | 2020 | 2021 | 2020 |
| Net cash flow used in operating activities | \$(108,242) | \$(165,607) | \$(104,058) | \$(160,891) |
| Net cash flows used in investing activities | (433) | (2,865) | (433) | (2,865) |
| Net cash flows provided by financing activities | 274 | 149,548 | (3,909) | 144,837 |
| Effect of exchange rate changes on cash and cash equivalents | (10,651) | 22,022 | (10,650) | 22,017 |
| Net (decrease) / increase in cash and cash equivalents | (119,051) | 3,097 | (119,051) | 3,097 |
| Net cash and cash equivalents at the beginning of the period | 196,352 | 193,255 | 196,352 | 193,255 |
| Net cash and cash equivalents at the end of the period | \$ 77,301 | \$ 196,352 | \$ 77,301 | \$ 196,352 |

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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) and the Company's ADSs (each representingone-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").

⁵ Unaudited financial statements prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union.



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, 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.

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