
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF THE
SECURITIES EXCHANGE ACT OF 1934**

For the month of April 2023

Commission File Number: 001-39446

CureVac N.V.

(Exact Name of Registrant as Specified in Its Charter)

**Friedrich-Miescher-Strasse 15, 72076
Tübingen, Germany
+49 7071 9883 0**

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F



Form 40-F



On April 25, 2023, CureVac N.V. (the “Company”) issued a press release announcing the Company’s financial results and business updates for the fourth quarter and full-year of 2022.

The information included in this Form 6-K (including Exhibit 99.1, but excluding the statements of the Company’s Chief Executive Officer and Chief Financial Officer contained in Exhibit 99.1 hereto) is hereby incorporated by reference into the Company’s Registration Statement on Form F-3 (File No. 333-259613).

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, thereunto duly authorized.

CUREVAC N.V.

By: /s/ Alexander Zehnder
Chief Executive Officer

Date: April 25, 2023

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
99.1	CureVac N.V. Press Release dated April 25, 2023

CureVac Announces Financial Results for the Fourth Quarter and Full-Year 2022 and Provides Business Update

- In 2022, ongoing business transformation driven by COVID-19 and flu clinical developments in collaboration with GSK and successful broadening of oncology footprint
- Early 2023, strong validation of CureVac's proprietary mRNA technology platform from positive preliminary Phase 1 data in COVID-19 and flu in collaboration with GSK
 - Monovalent modified COVID-19 candidate CV0501 demonstrated efficient booster activity and good tolerability across now available dose range of 3 to 200µg
 - Monovalent modified flu candidate Flu-SV-mRNA showed immunogenicity in line with licensed comparator at lowest dose of 2µg; strong performance in older adults
 - Modified mRNA technology selected as preferred technology; on track with new clinical studies in flu and COVID-19 in Q2 and later in 2023, with updated candidates
- On track with first proof-of-principle study in Q2 2023 for clinical validation of second-generation mRNA backbone in oncology
- Progressing proprietary LNP development programs for optimized and targeted mRNA delivery in prophylactic vaccines as well as cancer vaccines
- Cash and cash equivalents position of €495.8 million as of December 31, 2022
- \$250 million in gross proceeds raised with issuance of 27,027,028 common shares in February 2023 extend cash reach to mid-2025

TÜBINGEN, Germany/BOSTON, USA – April 25, 2023 – CureVac N.V. (Nasdaq: CVAC) (“CureVac”), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (“mRNA”), today announced financial results for the fourth quarter and full-year 2022 and provided a business update.

“Last year was transformative for CureVac, as we have made significant strides in advancing our unique end-to-end mRNA capabilities,” said Alexander Zehnder, Chief Executive Officer at CureVac. “We have successfully executed on clinical programs in COVID-19 and flu as demonstrated by positive preliminary data reported in early 2023, validating our differentiated mRNA technology platform. We have acquired and successfully integrated Frame Cancer Therapeutics, adding state-of-the-art antigen discovery technologies to our expanding oncology footprint. The German pandemic preparedness agreement reached in April 2022 has accelerated the build-up of our commercial-scale GMP IV plant as a safeguard against future infectious disease outbreaks, forming an integral part of our highly scalable manufacturing landscape. With these key achievements, we have reached an inflection point. Future success will depend on strong execution discipline, which we will focus in 2023 on later stage clinical trials in prophylactic vaccines and initial clinical developments in oncology. As CureVac's new CEO, I am deeply impressed by the vast potential of our technology as well as the scientific rigor and passion of our employees, and I am excited to build on our momentum to deliver on our goals in 2023.”

“In 2022, CureVac experienced another year of significant transformation. We advanced our development from a biotech to a fully integrated biopharma company and achieved key milestones in both our clinical and corporate growth,” said Pierre Kemula, Chief Financial Officer of CureVac. “Our 2022 income statement underlines this transformative period, phasing out the commitments related to our first-generation vaccine candidate and focusing on our second-generation programs co-financed by GSK, technical development and small to large scale manufacturing. The successful raise of \$250 million in gross proceeds this February has significantly extended our financial runway for continued execution on our priorities in 2023 and beyond.”

Selected Business Updates

Prophylactic Vaccines

Executing on Broad Second-Generation mRNA Vaccine Program, Jointly Developed with GSK

CureVac is executing on its broad clinical development program in prophylactic vaccines in collaboration with GSK and initiated four Phase 1 studies in COVID-19 and flu in 2022, testing both unmodified and modified mRNA candidates to identify the best performing candidate. Positive preliminary data reported in early 2023 confirmed modified mRNA as the preferred technology for further clinical development in the COVID-19 and seasonal flu vaccine program. All candidates are based on CureVac’s proprietary second-generation mRNA backbone, targeting improved intracellular mRNA translation for early and strong immune responses. The second-generation mRNA backbone is expected to enable flexible protection against one or more emerging COVID-19 variants as well as other infectious diseases, such as flu and potential combinations against different viruses.

On January 6 and January 30, 2023, CureVac announced positive preliminary data from ongoing Phase 1 clinical programs in COVID-19 and flu. Preliminary results generated in younger as well as older adult populations showed that the constructs elicited promising immune responses starting at low doses as well as good reactogenicity profiles in both indications.

In the COVID-19 Phase 1 trial, the reported preliminary data for the tested monovalent vaccine candidate, CV0501, are based on cohort sizes of up to 20 participants in the younger adults age group (age 18-64) and 10 participants in the older adults age group (age ≥65). Previously reported safety data covered the 12, 25, 50, 100 and 200µg dose groups in the younger adult age group. Newly available data from 3 and 6µg dose levels in this age group show a consistent safety profile. One grade 3 solicited adverse event occurred in the 3µg dose group reported as fatigue. In the older adult age group, safety data were initially reported for doses levels of 12, 25 and 50µg. Newly available safety data for the 100 and 200µg dose levels showed no grade 3 solicited adverse events at these dose levels in this age group. CV0501 was shown to be generally well tolerated across both age groups and all dose levels. Immunogenicity data for the full dose ranges in both age groups showed relevant titers of neutralizing antibodies beginning at the lowest tested dose.

On day 29 at the 12µg dose level, CV0501 generated a ratio of post-boost to pre-boost serum neutralizing titers against the Omicron BA.1 variant of 8.1 in younger adults and 13.3 in older adults. The data read-outs for both age groups are currently being finalized.

While CV0501 encodes the Omicron BA.1 variant, a Phase 2 clinical study, expected to start later in 2023, will assess monovalent and bivalent vaccine candidates designed to target clinically relevant variants.

In the flu Phase 1 trial, preliminary data were reported on the tested monovalent construct Flu-SV-mRNA, expressing an H1N1 hemagglutinin antigen (subtype of influenza A). A number of doses ranging from 2 to 54µg with up to 25 subjects per dose cohort were evaluated in younger adults (age 18-45). In this age group, preliminary safety and reactogenicity data showed that Flu-SV-mRNA was generally well tolerated with no safety concerns observed to date across all tested dose levels. A single dose of Flu-SV-mRNA was assessed for safety and reactogenicity in older adults (age 60-80) and was also observed to be safe and well tolerated with no grade 3 adverse events in the 32 subjects who were administered the mRNA construct. Immunogenicity of the monovalent Flu-SV-mRNA was assessed in parallel with a licensed seasonal flu vaccine comparator in both age groups. In younger adults, adjusted geometric mean hemagglutinin inhibition antibody titers increased up to approximately 3.3 times those elicited by the licensed flu vaccine comparator. In older adults, adjusted geometric mean hemagglutinin inhibition antibody titers were approximately 2.3 times those elicited by the licensed flu vaccine comparator. In the same age group, the percentage of subjects achieving seroconversion was 89.7% for Flu-SV-mRNA and 56.2% for the licensed flu vaccine comparator.

The vaccine candidate for future clinical development in flu is expected to be a multivalent candidate, targeting all four strains recommended by the WHO. A combined Phase 1/2 study for multivalent vaccine candidates is expected to start in the second quarter of 2023.

Oncology

Broadening of Oncology Footprint with mRNA Cancer Vaccines – Differentiated Antigen Discovery Approach

CureVac continues to execute on its strategy to develop the next generation of targeted mRNA-based cancer vaccines and expand in the oncology area with its differentiated antigen discovery approach. An initial portfolio of cancer vaccine candidates will be based on CureVac's second-generation mRNA backbone, supported by its recent clinical validation in prophylactic vaccines. CureVac focuses on two approaches 1) the development of off-the-shelf cancer vaccines based on tumor antigens shared by different cancer patients and 2) the development of fully personalized cancer vaccines based on a patient's individual tumor genomic profile. Innovation in cancer vaccine development is further enabled by CureVac's proprietary lipid nanoparticle (LNP) research to further enhance T cell mediated immune responses for strongly immunogenic cancer vaccine candidates.

A previously announced clinical proof-of-principle study, which is designed to validate and optimize the second-generation mRNA backbone in an oncology setting, is on track to start in the second quarter of 2023. The Phase 1 study will test a single mRNA construct encoding for eight epitopes from tumor-associated antigens to assess the safety, immunogenicity and T cell-mediated immune activation in patients with surgically resected glioblastoma. Successful study setup and manufacture of clinical trial material of the complex mRNA construct represent important milestones that have already been achieved well in advance of the Phase 1 study starting, which is expected to enroll up to 54 patients at clinical sites in Germany, Belgium and the Netherlands.

A second previously announced clinical proof-of-principle study in patients with melanoma was anticipated to start in the second half of 2023. Following an extensive portfolio review, CureVac has refocused its clinical development in oncology. Instead of a proof-of-principle study, featuring an established full-length shared tumor antigen, CureVac expects to initiate a Phase 1 study assessing a state-of-the-art multi-epitope design derived from CureVac's proprietary antigen discovery platform. The study, which will be conducted in combination with PD-1 antibodies, is expected to start in 2024.

Lipid Nanoparticle mRNA Delivery

CureVac is advancing its research on proprietary lipid nanoparticles (LNP) for improved and targeted mRNA delivery within the body. At the European Molecular Biology Organization (EMBO) workshop in April this year, the company presented data on mRNA-LNP complexes of varied composition exhibiting distinct biological activities that open new routes for bespoke applications in prophylactic and cancer vaccines.

The presented *in vitro* and preclinical data demonstrate that targeted changes to the ratio or composition of the LNP constituents can be applied to fine tune LNP physicochemical properties and elicit distinct immune responses and biological activities. These data complement previously reported data on a new PEG-free LNP delivery system, which was preclinically shown to provide highly localized transcription of mRNA in the immune compartment and to be highly stable at room temperature as a dried presentation for an extended period.

Financial Update for the Fourth Quarter and Full-Year of 2022

Cash Position

Cash and cash equivalents amounted to €495.8 million on December 31, 2022, down from €811.5 million in the previous year. In 2022, cash was used for the funding of CureVac's operations and R&D, the funding of the company's new commercial-scale manufacturing facility, GMP IV, and the settling of contract manufacturing organization (CMO) contracts as part of the wind-down activities for CVnCoV, the company's first-generation vaccine program. In 2021, cash used in operations was mainly allocated to prepayments to contract research organizations (CRO) and CMOs in relation to CVnCoV.

As of December 31, 2022, CureVac has settled most of its financial obligations related to CVnCoV. Looking forward, CureVac expects to see a decrease in cash outflows relating to the first-generation vaccine program. However, the company may have further cash outflows as it continues winding down CMO contracts associated with this program.

Revenues

Revenues amounted to €11.7 million and €67.4 million for the three and twelve months ended December 31, 2022, respectively, representing a decrease of €29.5 million and €35.6 million, from €41.2 million and €103.0 million, respectively, for the same periods in 2021.

The year-on-year decrease was primarily driven by the termination of the Boehringer Ingelheim collaboration in 2021, which led to revenue recognition of €26 million in that year.

Revenues from the two GSK collaborations decreased year-on-year by €12.0 million as the companies focused on the lead programs, flu and COVID-19. In the first quarter of 2022, CureVac received a €10 million milestone payment related to the initiation of the seasonal flu clinical trial. €6.3 million of this milestone was recognized pro rata as revenue in 2022. In 2022, total revenues of €62.3 million were recognized for both GSK collaboration agreements compared to €74.3 million in the prior year.

Operating Result

Operating loss amounted to €121.5 million and €249.5 million for the three and twelve months ended December 31, 2022, respectively, representing an increase of €116.0 million and a decrease of €162.8 million from an operating loss of €5.5 million and €412.3 million, respectively, for the same periods in 2021.

The operating result was affected by several key drivers:

- Cost of sales decreased primarily due to less expenses on CMO services. Prior year 2021 was impacted by significant expenses related to the set-up of a European CMO network for CVnCoV, CureVac's first-generation vaccine program, including recognition of liabilities associated with winding down CMO contracts. This was partially offset in 2022 by an increase in write-off for raw materials, following the transfer to another party of reserved production capacity at a CMO.
- Research and development expenses decreased year-on-year primarily due to the termination of the CVnCoV Phase 2b/3 clinical study. 2021 R&D costs were mainly driven by the 40,000 subject Phase 2b/3 clinical trial for CVnCoV. Additionally, 2022 R&D costs were positively impacted by two elements amounting to €63.6 million:
 - As of December 2021, CureVac had accrued all estimated remaining CVnCoV clinical trial costs. With the declining number of continuing study participants and re-negotiation of contracts in 2022, the remaining CVnCoV clinical trial costs estimate 6 decreased, resulting in the reversal of €38.5 million of the provision recorded in 2021.



This decrease was partially offset by increased materials consumed in research and development for the company's programs.

- Additionally, 2022 R&D costs were positively impacted by a net gain from a change in the estimate in CMO contract termination provisions of €25.1 million, resulting primarily from the transfer to another party of committed capacity at a CMO in the first quarter of 2022.
- The fourth quarter of 2021 was impacted by income of €574.5 million from the release of governmental contract liabilities, related to the upfront payment from the European Commission (EC) and the grant from the German Federal Ministry of Education and Research (BMBF) after the withdrawal of CVnCoV from the regulatory approval process in October 2021; no such income was recognized in 2022.
- Other income decreased year-on-year but was positively impacted by €32.5 million in compensation for the reimbursement by another party of pre-payments and production activities set-up at a CMO. In 2021, other income was primarily attributable to amounts recognized from grants from the BMBF.

Financial Result (Finance Income and Expenses)

Net financial result for the three and twelve months ended December 31, 2022, was negative with €7.2 million and positive with €0.3 million, respectively, representing a decrease of €8.2 million and increase of €0.5 million from a profit of €1.0 million and a loss of €0.2 million for the same periods in 2021. Financial result was driven by foreign exchange impacts and interest on cash investments.

Pre-Tax Loss

Pre-tax loss was €128.7 million and €249.2 million for the three and twelve months ended December 31, 2022, compared to €4.5 million and €412.5 million in the same respective periods of 2021.

Conference call and webcast details

Dial-in numbers to participate in the conference call:

U.S. Toll-Free: +1-877-407-0989

International: +1-201-389-0921

Germany: 0800 182 0040

The live webcast link can be accessed via the newsroom section of the CureVac website at <https://www.curevac.com/en/newsroom/events/>

Corresponding presentation slides will be posted shortly before the start of the webcast.

[A replay will be made available at this website after the event.](#)



About CureVac

CureVac (Nasdaq: CVAC) is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing, optimizing, and manufacturing this versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of optimized mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. In July 2020, CureVac entered in a collaboration with GSK to jointly develop new products in prophylactic vaccines for infectious diseases based on CureVac's second-generation mRNA technology. This collaboration was later extended to the development of second-generation COVID-19 vaccine candidates, and modified mRNA vaccine technologies. Based on its proprietary technology, CureVac has built a deep clinical pipeline across the areas of prophylactic vaccines, cancer therapies, antibody therapies, and the treatment of rare diseases. CureVac N.V. has its headquarters in Tübingen, Germany, and has more than 1,000 employees across its sites in Germany, the Netherlands, Belgium, Switzerland and the U.S. Further information can be found at www.curevac.com.

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Forward-Looking Statements CureVac

This press release contains statements that constitute “forward looking statements” as that term is defined in the United States Private Securities Litigation Reform Act of 1995, including statements that express the opinions, expectations, beliefs, plans, objectives, assumptions or projections of CureVac N.V. and/or its wholly owned subsidiaries CureVac SE, CureVac Manufacturing GmbH, CureVac Inc., CureVac Swiss AG, CureVac Corporate Services GmbH, CureVac RNA Printer GmbH, CureVac Belgium SA and CureVac Netherlands B.V. (the “company”) regarding future events or future results, in contrast with statements that reflect historical facts. Examples include statements regarding the completion, size and terms of the proposed public offering. In some cases, you can identify such forward-looking statements by terminology such as “anticipate,” “intend,” “believe,” “estimate,” “plan,” “seek,” “project,” or “expect,” “may,” “will,” “would,” “could,” “potential,” “intend,” or “should,” the negative of these terms or similar expressions. Forward-looking statements are based on management’s current beliefs and assumptions and on information currently available to the company. However, these forward-looking statements are not a guarantee of the company’s performance, and you should not place undue reliance on such statements. Forward-looking statements are subject to many risks, uncertainties and other variable circumstances, including negative worldwide economic conditions and ongoing instability and volatility in the worldwide financial markets, ability to obtain funding, ability to conduct current and future preclinical studies and clinical trials, the timing, expense and uncertainty of regulatory approval, reliance on third parties and collaboration partners, ability to commercialize products, ability to manufacture any products, possible changes in current and proposed legislation, regulations and governmental policies, pressures from increasing competition and consolidation in the company’s industry, the effects of the COVID-19 pandemic on the company’s business and results of operations, ability to manage growth, reliance on key personnel, reliance on intellectual property protection, ability to provide for patient safety, and fluctuations of operating results due to the effect of exchange rates or other factors. Such risks and uncertainties may cause the statements to be inaccurate and readers are cautioned not to place undue reliance on such statements. Many of these risks are outside of the company’s control and could cause its actual results to differ materially from those it thought would occur. The forward-looking statements included in this press release are made only as of the date hereof. The company does not undertake, and specifically declines, any obligation to update any such statements or to publicly announce the results of any revisions to any such statements to reflect future events or developments, except as required by law.

For further information, please reference the company’s reports and documents filed with the U.S. Securities and Exchange Commission (SEC). You may get these documents by visiting EDGAR on the SEC website at www.sec.gov.

Cash and Condensed Consolidated Profit and Loss Data

(in € millions)	December 31, 2021	December 31, 2022
Cash and Cash Equivalents	811.5	495.8

(in € millions)	Three months ended December 31,	
	2021	2022
Revenue	41.2	11.7
Cost of Sales, Operating Expenses & Other Operating Income	-46.7	-133.2
Operating Result	-5.5	-121.5
Financial Result	1.0	-7.2
Pre-Tax Loss	-4.5	-128.7

(in € millions)	Twelve months ended December 31,	
	2021	2022
	Summary of Audited Full Year Accounts	
Revenue	103.0	67.4
Cost of Sales, Operating Expenses & Other Operating Income	-515.3	-316.9
Operating Result	-412.3	-249.5
Financial Result	-0.2	0.3
Pre-Tax Loss	-412.5	-249.2