
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 May, 2021

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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

On May 26, 2021, CureVac N.V. (the “Company”) issued a press release announcing the Company’s financial results and business updates for the first quarter of 2021.

The information in this Form 6-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act.

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/ Franz-Werner Haas, LLD, LLM
Chief Executive Officer

Date: May 26, 2021

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

[99.1](#) [CureVac N.V. Press Release dated May 26, 2021.](#)



CureVac Announces Financial Results for the First Quarter of 2021 and Business Updates

- *First-Generation COVID-19 vaccine program, CVnCoV*
 - o *Phase 3 trial started with CVnCoV in adults suffering from selected comorbidities*
 - o *Phase 2a trial in Peru and Panama assessing third booster vaccination at one and six month post second dose*
 - o *CureVac participating in broad UK trial evaluating different COVID-19 vaccines as potential boosters at least three months following full primary vaccination*
- *First preclinical data of second-generation COVID-19 vaccine candidate, CV2CoV, demonstrates faster onset of antibody production and high variant cross-neutralization*
- *Rolling submission with Swissmedic initiated after filing of first data package*
- *Financials: cash position of €1.50 billion as of March 31, 2021*

TÜBINGEN, Germany/ BOSTON, USA – May 26, 2021 – CureVac N.V. (Nasdaq: CVAC), a global biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (“mRNA”), today announced business updates and financial results for the first quarter of 2021.

“The COVID-19 reality has changed dramatically since the beginning of this year and is today characterized by the rapid spread of Variants of Concern as well as the emergence of new strains, which together have now all but supplanted the original virus strain that we fought throughout 2020,” said Franz-Werner Haas, Chief Executive Officer of CureVac. “In this variant rich environment, we are convinced that our first-generation COVID-19 vaccine candidate, CVnCoV, will make an important contribution to the pandemic vaccination programs, for which availability of potent vaccines is now more important than ever to stop the virus from evolving further. CVnCoV is in the final stage of clinical development in what we believe is one of the most diverse efficacy trials in terms of the range of virus variants. For CVnCoV, which we advance together with our partner Bayer, we are expecting the data readout from the pivotal Phase 2b/3 trial in the second quarter, which will enable us to finalize our rolling submission with EMA. Our second-generation vaccine candidate, CV2CoV, is developed together with GSK and is planned to enter clinic trials in the third quarter of 2021. First preclinical data showed high potential for even lower doses that is expected to enable multivalent or combination vaccines to flexibly address different variants or different diseases in one vaccine.”

“In the first quarter of 2021, we were able to continue to build and strengthen our strong cash position with our first follow-on financing in February 2021, raising \$517.5 million in aggregated gross proceeds,” said Pierre Kemula, Chief Financial Officer of CureVac. “Together with our strategic partners Bayer and GSK, we are fully dedicated to create sustainable value with our COVID-19 vaccine program – for the pandemic and beyond. This is further enabled by the ongoing ramp-up of our broad and integrated European manufacturing network as well as the RNA Printer, our autonomous and mobile manufacturing unit well suited to address pandemic preparedness. Build-up of our commercial infrastructure is progressing well as we prepare to potentially launch our first product and work toward our goal of becoming an integrated biopharma company.”

Selected Business Updates

CVnCoV – First-Generation COVID-19 Vaccine Candidate

CVnCoV is CureVac's first-generation vaccine candidate in its clinical COVID-19 vaccine program. Based on optimized, non-chemically modified mRNA, CVnCoV was shown to be well tolerated and induced robust immune responses at a 12µg dose in our Phase 1 clinical trial. Additionally, CVnCoV has shown to enable delivery logistics at standard refrigerator temperature – a critical advantage as the world faces a pandemic that demands safe vaccines produced and distributed on a global scale.

Phase 3 in Belgium Including Participants with Comorbidities

A Phase 3 trial to evaluate the safety, reactogenicity and immunogenicity of CVnCoV in adults with an elevated risk of severe COVID-19 disease due to comorbidities started in late April with vaccination of the first participant. The multicenter trial includes people with selected comorbidities such as obesity, chronic cardiovascular disease, chronic kidney disease, chronic obstructive pulmonary disease (COPD), HIV, type 2 diabetes mellitus and post-renal transplantation. It is currently being conducted in Belgium and is expected to enroll approximately 1,200 participants.

Phase 2a in Peru and Panama

To offer the best protection in the context of spreading virus variants, additional data is needed concerning the longevity of protection of current vaccines, as well as the need for and timing of potential booster vaccination.

CureVac is currently assessing the benefit of a booster vaccination in its clinical Phase 2a trial in Peru and Panama. The Phase 2a trial, which serves as a dose-confirmation trial of a 12µg dose of CVnCoV for advanced clinical testing, is fully recruited at 674 participants and features approximately 270 participants in the important group above the age of 60, who received 12µg of CVnCoV. To assess the age-related need for a booster vaccination, the two-dose vaccination schedule was further extended by a third booster vaccination, administered to trial participants above the age of 60 one month after the second dose and to all trial participants above the age of 18 six months after the second dose. No increase in reactogenicity was observed following administration of the booster vaccination compared to administration of the two doses of the primary vaccination.

Inclusion of CVnCoV in UK COVID-19 Cov-Boost Vaccine Study

On May 19, the UK Government announced the upcoming Cov-Boost trial, further extending current clinical research of booster vaccinations by investigating whether it is safe and effective to boost using a different vaccine from the one originally used for immunization.

The study, which is the first of its kind, is scheduled to start at the beginning of June. It will be conducted at 18 sites across the UK and is expected to include a total of 2,886 participants. Cov-Boost will evaluate several different COVID-19 vaccines as potential boosters, including CVnCoV, administered at least three months after participants have received their second initial vaccine dose. Each participant will receive one booster vaccine, which could be different from the one they have already received. Initial results of the study are expected in September 2021.

Regulatory Pathway

CureVac's recently founded Swiss subsidiary announced the initiation of a rolling submission process with the Swiss regulatory authority Swissmedic on April 19, 2021. Regulatory clearance of CVnCoV with Swissmedic will allow CureVac to serve the order of the Swiss federal government for the supply of five million vaccine doses, which forms part of the delivery agreement between the European Commission and CureVac. Next to Germany and Austria, Switzerland represents one of the three countries for which CureVac holds exclusive commercialization rights for Program Products in the context of its broad GSK partnership in vaccines for infectious diseases as well as second-generation vaccines for COVID-19.

CV2CoV – Second-Generation COVID-19 Vaccine Candidate

CV2CoV is CureVac's second-generation vaccine candidate in its COVID-19 vaccine program, developed in collaboration with GSK. Also based on non-chemically modified mRNA, CV2CoV features a new mRNA backbone optimized to improve intracellular mRNA translation for increased and extended protein expression. CV2CoV optimizations target strong immune responses at even lower doses compared to CVnCoV and could support the development of multivalent vaccines to target rapidly spreading COVID-19 variants. First clinical trials for CV2CoV are expected to start in the third quarter of 2021.

First Preclinical Study of CV2CoV on Immunogenicity and Variant Cross-Neutralization

On May 13, CureVac published the first preclinical data of its second-generation COVID-19 vaccine candidate, CV2CoV, demonstrating high levels of antigen production in an *in vitro* setup as well as strong and dose-dependent immune responses in an established rat model. Preclinical data in animals immunized with two doses of CV2CoV in the dose range of 0.5-40µg demonstrated fast onset of strong immune responses already after the first dose. In addition, the serum of vaccinated animals showed significant cross-neutralization against variants first discovered in Denmark (B.1.1.298), the UK (B.1.1.7) and South Africa (B.1.351). The full manuscript is available on the pre-print server [bioRxiv](#).

Financial Update for the First Quarter of 2021

Cash Position

Cash and cash equivalents increased from €1,323 million as of December 31, 2020, to €1,497 million as of March 31, 2021, mainly due to the raising of €405 million in net proceeds in a follow-on public offering, which closed in February 2021. In the first three months of 2021, cash used in operations was mainly used to advance all R&D activities for CVnCoV, our first-generation COVID-19 vaccine candidate.

Revenues

Revenue was €10.0 million for the first three months of 2021, representing an increase of €6.9 million or 221.6% compared to revenue of €3.1 million for the same period in 2020.

This increase was primarily driven by €9.1 million in revenue recognized under our collaboration agreement with GlaxoSmithKline plc (GSK), entered into in July 2020, for the research, development, manufacturing and commercialization of mRNA-based vaccines and monoclonal antibodies targeting infectious disease pathogens. In the first three months of 2020, revenue primarily consisted of €2.0 million recognized under our collaboration with Eli Lilly, which terminated later in June 2020.

Operating result

Operating loss was €115.8 million for the first three months of 2021, representing an increase of €92.6 million, or 339.0%, from operating loss of €23.2 million for the same period in 2020.

This increase in operating loss was mainly driven by higher research and development costs from our ongoing Phase 2/3 clinical trials of CVnCoV. Such increased R&D costs consist primarily of cost incurred to clinical research organizations and for personnel costs for employees involved in the CVnCoV development, as well as materials used in the administration of CVnCoV clinical trials. We also recognized increased cost of sales mainly due to set-up activities for production processes for our COVID-19 vaccine candidate. Additionally, we recognized increased general and administrative expenses mainly due to consulting services for product launch readiness and personnel-related costs from an increased headcount. These increases in expenses were partially offset by other operating income recognized under our grant from the German Federal Ministry of Education and Research (BMBF) for the development and production of our COVID-19 vaccine candidate.

Financial Result

Financial result for the first three months of 2021 was a gain of €3.6 million, representing an increase of €4.3 million, or 630.9%, from a loss of €0.7 million for the same period in 2020. This net gain was driven mainly by foreign exchange gains, which were partly offset by negative interest on cash, which is being held in liquid funds to be available for use in our CVnCoV R&D and manufacturing activities.

Pre-Tax Loss

Pre-tax loss was €112.2 million for the first three months of 2021, compared to €23.9 million for the same period in 2020.

About CVnCoV

CureVac began development of mRNA-based COVID-19 vaccine candidates in January 2020. The vaccine candidate chosen for first clinical development, CVnCoV, is an optimized, non-chemically modified mRNA, encoding the prefusion stabilized full-length spike protein of the SARS-CoV-2 virus, and formulated within Lipid Nanoparticles (LNPs). Phase 1 and 2a clinical trials of CVnCoV began in June and September 2020, respectively. Phase 1 interim data reported in November 2020 showed that CVnCoV was generally well tolerated across all tested doses and induced strong antibody responses in addition to first indication of T cell activation. The quality of the immune response was comparable to recovered COVID-19 patients, closely mimicking the immune response after natural COVID-19 infection. In December 2020, CureVac initiated a pivotal Phase 2b/3, the HERALD study, with a 12µg dose of CVnCoV. In February 2021, CureVac initiated a rolling submission with the European Medicines Agency (EMA) for CVnCoV.

About CureVac

CureVac is a global biopharmaceutical company in the field of messenger RNA (mRNA) technology, with more than 20 years of expertise in developing and optimizing the versatile biological molecule for medical purposes. The principle of CureVac's proprietary technology is the use of non-chemically modified mRNA as a data carrier to instruct the human body to produce its own proteins capable of fighting a broad range of diseases. 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 had its initial public offering on the New York Nasdaq in August 2020. It is headquartered in Tübingen, Germany, and employs more than 600 people at its sites in Tübingen, Frankfurt, and Boston, USA. 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 AG, CureVac Real Estate GmbH, CureVac Inc. and CureVac Swiss AG (the “company”) regarding future events or future results, in contrast with statements that reflect historical facts. Examples include discussion of the potential efficacy of the company’s vaccine and treatment candidates and the company’s strategies, financing plans, growth opportunities and market growth. 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, 2020	March 31, 2021
		(unaudited)
Cash and Cash Equivalents	1,322.6	1,496.9

(in € millions)	Three months ended March 31,	
	2020	2021
	(unaudited)	(unaudited)
Revenue	3.1	10.0
Cost of Sales, Operating Expenses & Other Operating Income	-26.3	-125.8
Operating Result	-23.2	-115.8
Financial Result	-0.7	3.6
Pre-Tax Loss	-23.9	-112.2