
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 August, 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 August 16, 2021, CureVac N.V. (the “Company”) issued a press release announcing the Company’s financial results and business updates for the second quarter and first half 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: August 16, 2021

EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
99.1	CureVac N.V. Press Release dated August 16, 2021.



CureVac Announces Financial Results for the Second Quarter and First Half of 2021 and Provides Business Update

- Continuation of corporate transformation into commercial-ready biopharma company
 - o Management team strengthened with appointments of Chief Operating Officer Malte Greune and Chief Development Officer Klaus Edvardsen
- First-generation COVID-19 vaccine candidate, CVnCoV
 - o Final analysis reported of pivotal Phase 2b/3 study conducted in ten countries in variant-dominated environment
 - o Committed to seeking regulatory approval with EMA – submission of comprehensive clinical data packages within rolling submission ongoing
- Second-generation COVID-19 vaccine candidate, CV2CoV, jointly advanced with GSK
 - o Preclinical study provides evidence for strongly improved immune responses with second-generation mRNA backbone compared to first-generation backbone during challenge study and against range of variants, including Delta and Lambda variant
 - o Start of CV2CoV Phase 1 clinical trial anticipated in Q4 2021
- Oncology Programs
 - o Phase 1 trial extension of lead asset, CV8102, on track to fully recruit
 - o Legacy program, BI 1361849, developed in partnership with Boehringer Ingelheim, based on early protamine formulation terminated; companies assessing options for further collaboration
- Financials: Cash position of €1.36 billion as of June 30, 2021

TÜBINGEN, Germany/ BOSTON, USA – August 16, 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 financial results for the second quarter and first half of 2021 and provided business update.

“Large parts of the world are still under-vaccinated against SARS-CoV-2, making effective vaccines necessary to prevent further evolution of the virus and to avoid renewed restrictions on public life,” said Franz-Werner Haas, Chief Executive Officer of CureVac. “While the recently reported final data from our pivotal Phase 2b/3 study have fallen short of expectations in older adults, our first-generation COVID-19 vaccine candidate, CVnCoV, has shown a solid efficacy profile in the age group of 18 to 60. We are reaffirming our intention to seek regulatory approval with the European Medicines agency and are currently submitting extensive clinical data to the agency to allow for the assessment of CVnCoV’s public health benefit. Insights from our COVID-19 development program are feeding into all areas of our pipeline, where we are pursuing a broader technology approach and multivalent as well as combination vaccine formats, as part of the large infectious diseases program jointly developed with GSK. This includes our second-generation COVID-19 vaccine candidate, CV2CoV, which is advancing on track to enter clinical development in Q4 2021. In parallel, we are accelerating the development of the organization and the expansion of our manufacturing capacity, including the capacity for more clinical trials, while creating a strong development focus for The RNA Printer[®] via a separate operational infrastructure for this strategic key project.”

“Our financing activities, as well as the extension of our GSK partnership in the first half of 2021, provide an important financial foundation for accelerating our business expansion, while hedging the associated scale-up costs,” said Pierre Kemula, Chief Financial Officer of CureVac. “We closed the first half of 2021 with approximately €1.36 billion in cash, which allows us to further grow our infrastructure for commercial product development in all areas and manufacturing supported by new members to the CureVac management team. While we are working toward regulatory approval of CVnCoV, we are expanding our clinical pipeline through the broad infectious disease portfolio we are developing together with GSK, including our second-generation COVID-19 vaccine program.”

Selected Business Updates

Executing on Corporate Development and Business Transformation

CureVac is rapidly advancing the corporate transformation from a research-oriented biotech to a commercial-ready biopharma company. Continued build-up of a commercial infrastructure was recently supported by the appointment of two new CureVac management team members that bring deep international expertise and experienced leadership.

Dr. Malte Greune was appointed to the CureVac Management Team as Chief Operating Officer on July 1, 2021. He will be focused on further enabling CureVac’s comprehensive strategy for expansion of all commercial manufacturing activities and operations for mRNA vaccines and therapeutics. On August 1, 2021, Dr. Klaus Edvardsen joined CureVac as Chief Development Officer to advance the technology platform and grow the CureVac clinical development pipeline in all therapeutic areas.

Prophylactic Vaccines

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 at a 12µg dose and to induce robust immune responses comparable to those observed in recovered COVID-19 patients.

Pivotal Phase 2b/3 (HERALD) in Europe and Latin America

The pivotal Phase 2b/3 study (HERALD), initiated in December 2020, enrolled approximately 40,000 participants in ten countries in Europe and Latin America in the predefined age groups of 18 to 60 and above the age of 60. Of those participants, approximately 75% were enrolled in sites in Latin America and 25% were enrolled in sites in Europe.

On June 30, 2021, data of the final analysis was reported based on 228 adjudicated COVID-19 cases, occurring at least two weeks after administration of the second dose. In the unprecedented context of 15 different virus variants circulating within the study population at the time of final analysis, CVnCoV demonstrated an overall vaccine efficacy of 48% against COVID-19 disease of any severity across all age groups. CVnCoV demonstrated significant protection among participants in the age group of 18 to 60, with an efficacy of 53% against disease of any severity, including single non-respiratory mild symptoms. Protection against moderate to severe disease was calculated to be 77% in the age group of 18 to 60. In the same age group, CVnCoV provided 100% protection against hospitalization or death. In participants above 60 years, the available data did not enable a statistically significant determination of efficacy. The data further confirmed the favorable safety profile of CVnCoV in all age groups.

Out of the 228 adjudicated cases, 204 were sequenced to identify the variant causing the infection. Approximately 86% of these cases were caused by Variants of Concern (~51%) and Variants of Interest (~35%), the latter including the Lambda strain first identified in Peru (~21%) and B.1.621, first identified in Colombia (~14%). Approximately 3% of cases were attributable to the original SARS-CoV-2 virus. The remaining 11% were caused by less-explored strains. In the age group of 18 to 60, across strains of higher prevalence, strain-dependent vaccine efficacy ranged from approximately 42% (B.1.621 variant, first identified in Colombia) up to 67% (Gamma variant) against any severity of disease. The Delta variant was not represented in the pool of adjudicated cases and could therefore not be separately assessed.

Regulatory Pathway

CureVac intends to apply for regulatory approval of CVnCoV with the European Medicines Agency (EMA), to leverage the vaccine's strengths in the age segment of the population where it provides demonstrated protection. Within the rolling submission initiated with the EMA in February 2021, submission of comprehensive clinical data packages is ongoing and is expected to be finalized toward the end of the third quarter. The potential subsequent application for conditional approval will be informed by continuing interactions with EMA.

Recent Amendments to the Clinical CVnCoV Development Program

The protocol amendment for the ongoing Phase 2a study in Peru and Panama, filed in March 2021 for the enrollment 40 adolescent participants between the ages of 12 and 17, has been withdrawn. A separate study to test CVnCoV in this highly important age-group is currently being prepared.

The Phase 3 trial, started in April 2021 to evaluate the safety, reactogenicity and immunogenicity of CVnCoV in adults with an elevated risk of severe COVID-19 infection due to comorbidities, is ongoing. Due to the advancement of the vaccination program in Belgium where the study is conducted, including this particularly vulnerable population, the study will continue with a reduced number of 131 recruited participants.

The flu-co-administration study, planned to be initiated together with Bayer to assess compatibility with established seasonal vaccines in case of seasonal COVID-19 vaccinations, is currently being redesigned based on inconclusive efficacy of CVnCoV in adults above the age of 60 in the HERALD study.

A Phase 2 study, focusing on immunogenicity and a deep characterization of immune responses in older adults above the age of 65 compared to younger adults was cancelled based on inconclusive efficacy of CVnCoV in adults above the age of 60 in the HERALD study.

CV2CoV – Second-Generation COVID-19 Vaccine Candidate

CV2CoV is CureVac's second-generation vaccine candidate in its COVID-19 vaccine program, featuring a new mRNA backbone, jointly advanced with GSK. The optimized mRNA backbone targets improved intracellular mRNA translation for increased and extended protein expression, resulting in earlier and stronger immune responses compared to CVnCoV.

Preclinical Study of CV2CoV on Immune Responses and Protection against Virus Challenge

On August 16, CureVac published preclinical data, characterizing immune responses as well as the protective efficacy of CV2CoV and CureVac's first-generation vaccine candidate, CVnCoV, against SARS-CoV-2 challenge in non-human primates. The study assessed cynomolgus macaques vaccinated with 12µg of either the first- or second-generation vaccine candidate. Better activation of innate and adaptive immune responses was achieved with CV2CoV compared to CVnCoV, resulting in faster response onset, higher titers of antibodies and stronger memory B and T cell activation. Higher antibody neutralizing capacity was observed with CV2CoV across all selected variants, including the Beta, Delta and Lambda variants. During challenge with the original SARS-CoV-2 virus, animals vaccinated with CV2CoV were found to be better protected based on highly effective clearance of the virus in the lungs and nasal passages. The full manuscript of the preclinical data is available on the pre-print server bioRxiv.

Following the current preclinical development of CV2CoV, a Phase 1 clinical trial is expected to start in Q4 2021.

Oncology

CV8102 – Cancer immuno-modulator in solid tumors

CureVac's lead oncology candidate, CV8102, is being assessed in a Phase 1 dose-escalation study, evaluating tolerability and activity as a single agent and in combination with systemic anti-PD-1 antibodies. An expansion part of the Phase 1 trial, announced in February 2021, aims to confirm the safety, tolerability and efficacy of CV8102 at a preferred 600µg dose in 40 patients with a focus on PD-1 refractory melanoma. As of July 6, 12 out of 30 patients had been successfully recruited to receive intra-tumoral injections of CV8102 in combination with PD-1 antibodies. In the group assigned for CV8102 single-agent treatment, recruitment has been completed with 10 out of 10 patients. Updates on the progress of the trial are expected at the European Society for Medical Oncology (ESMO) congress and the Society for Immunotherapy of Cancer (SITC) annual meeting later this year.

BI1361849 – Boehringer Ingelheim Collaboration

In June 2021, Boehringer Ingelheim expressed its intention to terminate the 2014 collaboration agreement on BI1361849. The termination will become effective in November 2021. The legacy program, targeting specific immune responses against tumor-associated antigens frequently overexpressed in patients with non-small cell lung cancer (NSCLC), applies an older protamine formulation technology, which reflected the state of the technology development at the time. A Phase 1/2 clinical trial in NSCLC applying BI1361849 as a combination therapy is ongoing. Both companies are currently assessing options to continue a collaboration on CureVac's RNA technology platform based on state-of-the-art LNP-based formulations.

Financial Update for the Second Quarter and First Half of 2021

Cash Position

Cash and cash equivalents increased to €1,355.8 million as of June 30, 2021, from €1,322.6 million as of December 31, 2020. This is mainly related to the raising of €404 million in net proceeds in a follow-on public offering in the first quarter of the year and to an upfront payment of €75 million received in May 2021 related to our collaboration with GSK on our second-generation COVID-19 vaccine candidate, CV2CoV. In the first six months of 2021, cash used in operations was mainly for the advancement of all R&D activities for CVnCoV, our first-generation COVID-19 vaccine candidate.

Revenues

Revenues amounted to €22.4 million and €32.4 million for the three and six months ended June 30 2021, representing a decrease of €12.1 million and €5.3 million, or 35% and 14%, from €34.5 million and €37.7 million for the same periods in 2020.

The decreases were primarily driven by the second quarter of 2020 having benefitted from a one-time effect whereby €33.1 million in contract liabilities from an upfront payment were recognized as revenue upon termination of our License and Collaboration Agreement with Eli Lilly.

This decrease was partially offset by increased revenues from our collaborations with GSK; in July 2020, GSK and CureVac signed a strategic collaboration agreement for the research, development, manufacturing and commercialization of mRNA-based vaccines and monoclonal antibodies targeting infectious disease pathogens. In April 2021, GSK and CureVac signed the COVID Collaboration and License Agreement for a second-generation COVID-19 vaccine program (CV2CoV). In total, for both programs, in the first six months 2021, revenue of €29.3 million was recognized. In addition, in June 2021, Boehringer Ingelheim informed CureVac of its intention to terminate the collaboration agreement for BI1361849. The termination will become effective in November 2021. As a result of the announced termination, the remaining contract liability, related to the upfront payment, is being recognized over a shorter period through the anticipated termination date. For the first six months of 2021, €2.1 million, compared to €1.0 million in the prior year, was recognized as revenue.

Operating Result

Operating loss amounted to €147.8 million and €263.7 million for the three and six months ended June 30, 2021, representing an increase of €144.6 million and €237.3 million from €3.2 million and €26.4 million for the same periods in 2020. The main driver of the increase in operating loss was higher research and development costs for CVnCoV, our COVID-19 vaccine candidate. These R&D costs consist primarily of costs related to clinical research organizations and to personnel involved in CVnCoV development. We also recognized increased cost of sales mainly due to set-up activities for production processes for our first-generation COVID-19 vaccine candidate, CVnCoV. The increase of cost of sales was also driven by a one-off recognition of expense related to ineffective set-up activities. The growth in general and administrative expenses was mainly due to consulting services for product launch readiness and personnel-related costs from an increased headcount. This increase in expenses was partially offset by a significant increase in other operating Income driven by 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 Income and Expenses)

The financial results for the three and six months ended June 30, 2021 were a loss, on a net basis, of €4.4 million and €0.7 million, respectively, representing an increase of €4.4 million and €8.8 million, from a loss of €8.8 million and €9.5 million for the same periods in 2020. Financial result for the six months ended June 30, 2021, was mainly driven by negative interest on cash, which is being held in liquid funds to be available for use for CVnCoV and CV2CoV development and manufacturing activities, but was almost fully offset by foreign exchange gains. The financial result for the six months ended June 30 2020, was mainly driven by interest recognized on convertible loans which were fully repaid in August 2020, and was partially offset by foreign exchange gains

Pre-Tax Loss

Pre-tax losses were €152.2 million and €264.4 million for the three and six months ended June 30, 2021, respectively, compared to €12.0 million and €35.9 million in the same respective periods of 2020.

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 700 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., CureVac Swiss AG and CureVac Corporate Services GmbH (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	June 30, 2021
		(unaudited)
Cash and Cash Equivalents	1,322.6	1,355.8

(in € millions)	Three months ended June 30,	
	2020	2021
	(unaudited)	(unaudited)
Revenue	34.5	22.4
Cost of Sales, Operating Expenses & Other Operating Income	-37.7	-170.2
Operating Result	-3.2	-147.8
Financial Result	-8.8	-4.4
Pre-Tax Loss	-12.0	-152.2

(in € millions)	Six months ended June 30,	
	2020	2021
	(unaudited)	(unaudited)
Revenue	37.7	32.4
Cost of Sales, Operating Expenses & Other Operating Income	-64.1	-296.1
Operating Result	-26.4	-263.7
Financial Result	-9.5	-0.7
Pre-Tax Loss	-35.9	-264.4