

CureVac Announces Financial Results for the Third Quarter and First Nine Months of 2023 and Provides Business Update

- Enrollment completed for Phase 2 COVID-19 study with mono- and bivalent vaccine candidates; study on track for data read-out in early 2024
- First participant dosed in seasonal flu Phase 2 study with potentially differentiated multivalent candidate; €15 million milestone payment by GSK triggered
- Phase 1 study in glioblastoma well on track with opening of third dose level for CVGBM, CureVac's multiepitope cancer vaccine candidate
- Preclinical data with multiepitope construct in oncology shows strong T cells responses and significantly extended survival in checkpoint-inhibitor resistant melanoma model
- Infringement ruling on four intellectual property rights postponed by Regional Court Düsseldorf pending separate validity ruling in German patent litigation against BioNTech; postponement suggests court will find all four rights to be infringed
- The RNA Printer® achieved first milestone, obtaining manufacturing license for GMP-grade mRNA manufacturing in cancer vaccine development
- Chief Business and Commercial Officer to leave CureVac at the end of his term, effective November 30, 2023
- Cash and cash equivalents position of €464.1 million as of September 30, 2023
- CureVac to host conference call and webcast today at 9 a.m. ET / 3 p.m. CET

TÜBINGEN, Germany/BOSTON, USA – November 14, 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 third quarter and first nine months of 2023 and provided a business update.

"We began 2023 with promising data out of our seasonal flu and COVID-19 programs and have maintained strong forward momentum in the clinical advancement of those vaccines as well as in oncology, where we recently opened the third cohort of our Phase 1 trial in glioblastoma. With both of our infectious disease programs now in Phase 2 and set to produce topline data in early 2024, we are delivering across our strategic priorities," said Dr. Alexander Zehnder, Chief Executive Officer of CureVac. "At the same time, we have made progress toward the recognition of our intellectual property rights with recent favorable developments in German courts."

"The focused execution on our clinical development programs in 2023 has been accompanied by important financial milestones, including our successful follow-on offering in February 2023. We also triggered a second developmental milestone payment of €15 million from GSK when our joint seasonal flu vaccine program advanced to Phase 2," said Pierre Kemula, Chief Financial Officer of CureVac. "These milestones enable us to reaffirm our cash runway until mid-2025, supported by an even more disciplined focus on cost management going into 2024."

Selected Business Updates

Prophylactic Vaccines

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

CureVac continues to advance its broad clinical development program in prophylactic vaccines in collaboration with GSK. Positive preliminary data reported in early 2023 in COVID-19 and flu provided strong validation of CureVac's mRNA technology platform. All jointly tested candidates are based on CureVac's proprietary second-generation mRNA backbone, targeting improved intracellular mRNA translation for early and strong immune responses.

Seasonal Influenza Program

In the ongoing Phase 1/2 study in seasonal influenza, CureVac announced dosing of the first participant in the Phase 2 part of the study on November 1, following the selection of a promising vaccine candidate based on positive Phase 1 interim data announced [September 12](#). The potentially differentiated, multivalent candidate encodes antigens matched to all WHO-recommended flu strains. It was selected from the Phase 1 part of the study that compared a comprehensive series of multivalent, modified mRNA seasonal flu vaccine candidates with up to eight separate mRNA constructs per candidate at different dose levels in 270 healthy younger adults (age 18-50). Interim Phase 1 safety data showed no safety concerns across all dose levels for the multivalent candidates. Humoral responses supported the selection of the preferred vaccine candidate for further evaluation in Phase 2. In Phase 2, the selected candidate will be tested in younger and older adults at different dose levels and compared to age-appropriate licensed seasonal flu comparator vaccines. Data are expected in 2024.

COVID-19 Program

Recruitment for the ongoing Phase 2 study in COVID-19 was completed at 427 randomized participants after dosing of the first participant was announced in [August 2023](#). The study assesses the safety and immunogenicity of different single booster doses of two modified mRNA COVID-19 vaccine candidates: the monovalent candidate, CV0601, encoding the spike protein of the omicron BA.4-5 variant and the bivalent candidate, CV0701, encoding the spike protein of the omicron BA.4-5 variant as well as the original SARS-CoV-2 strain. Vaccine candidates are compared to a licensed or authorized bivalent mRNA COVID-19 comparator vaccine. Interim Phase 2 data are expected in early 2024 and will inform the design of a pivotal Phase 3 study planned to start in 2024. The Phase 3 study is expected to feature an updated vaccine candidate and comparator vaccine according to the latest COVID-19 standard-of-care.

Oncology

Broadening of Oncology Footprint with mRNA Cancer Vaccines

CureVac continues to execute on its strategy to develop the next generation of targeted mRNA-based cancer vaccines based on cutting-edge technologies for antigen discovery combined with CureVac's second-generation mRNA backbone.

The strategy focuses on two approaches: 1) the development of off-the-shelf cancer vaccines based on tumor antigens shared across different cancer indications and 2) the development of fully personalized cancer vaccines based on a patient's individual tumor genomic profile.

Clinical off-the-shelf program in glioblastoma

CureVac's Phase 1 study of patients with resected glioblastoma is on track without any dose limiting toxicities and has escalated to the third dose level after dosing the first patient with its multiepitope cancer vaccine candidate, CVGBM, in [June 2023](#).

The open-label study evaluates the safety and tolerability of CVGBM in up to 54 patients with newly diagnosed and surgically resected MGMT-unmethylated glioblastoma or astrocytoma with a molecular signature of glioblastoma. CVGBM features a single unmodified mRNA encoding eight epitopes derived from known tumor-associated antigens with demonstrated immunogenicity in glioblastoma. A first data readout is expected in the second half of 2024.

More information can be found at [clinicaltrials.gov \(NCT05938387\)](https://clinicaltrials.gov/ct2/show/study/NCT05938387).

Preclinical Research in Oncology

CureVac recently presented preclinical studies supporting the potency of a multiepitope mRNA cancer vaccine construct targeting tumors in a murine melanoma model. The data support the evaluation of CVGBM, CureVac's multiepitope cancer vaccine candidate currently being tested in a Phase 1 study in patients with resected glioblastoma. The preclinical data were presented at the 11th International mRNA Health Conference, hosted by CureVac on October 31 - November 2, 2023, in Berlin, Germany.

A multiepitope mRNA construct encoding ten epitopes derived from the murine B.16.F10 melanoma cell line was tested in mice. The study applied three 5 µg doses of LNP-formulated B.16 mRNA, administered intramuscularly at weekly intervals. Data obtained on day 21 confirmed prominent induction of CD8+ and CD4+ T cell responses recognizing epitopes across the full multiepitope construct. Median survival of the animals increased to 30.9 days for treated mice compared to 23.2 days for a group vaccinated with formulated control mRNA.

Strong T cell activation is particularly encouraging and relevant, as the B16-F10 tumor model is characterized as a cytokine deficient "cold" tumor model that exhibits only very little immune cell infiltration and resistance to check-point inhibitors. The data suggest that single-agent application of the multiepitope B.16 mRNA construct generated robust T cell activation in the tumor microenvironment, thereby inhibiting tumor growth and extending survival in the applied preclinical model.

The RNA Printer® in Oncology

The RNA Printer®, CureVac's end-to-end solution for integrated and automated manufacturing of GMP-grade mRNA vaccines and therapeutics, successfully achieved the first milestone in an ongoing regulatory review process by obtaining a manufacturing license for an mRNA in the cancer vaccine development program to support CureVac's oncology strategy.

Designed to produce small-scale quantities through an automated process, The RNA Printer® is expected to support rapid and flexible provision of clinical trial material to screen and advance new antigens into clinical studies. Regulatory review is ongoing for an advanced approval to cover fully formulated vaccine candidates. Extension of manufacturing licenses to include a so-called framework license will ultimately allow for greater regulatory freedom and flexibility to manufacture different mRNA cancer vaccine candidates.

Protection of Intellectual Property Rights

Over the last 23 years, CureVac has developed proprietary foundational technology related to mRNA design, delivery and manufacturing that has materially contributed to the development of safe and efficacious COVID-19 vaccines.

CureVac is asserting its intellectual property rights in litigation against Pfizer/BioNTech in Germany, the U.S. and the UK. In Germany, where eight intellectual property rights are at issue, the Regional Court Düsseldorf chose to postpone a ruling on infringement on [September 28](#), for four out of the eight rights until challenges made by BioNTech to their validity have been decided by the relevant patent offices.

CureVac considers the postponement a favorable outcome as German courts typically delay infringement proceedings to wait for a decision on validity only if the challenged intellectual property right is in fact considered infringed. The postponement of the infringement ruling has no effect on the expected validity ruling. It does not reflect a preliminary assessment of validity, which can be determined only by the responsible and technically qualified patent authorities.

In the U.S., a trial date has been confirmed for October 1, 2024. The U.S. District Court for the Eastern District of Virginia will adjudicate infringement, validity, and damages in a single jury trial. In the U.S., CureVac's counterclaim to a Declarative Judgment Action by Pfizer/BioNTech in July 2022 proceeds under ten of its U.S. patents.

CureVac, as the earliest pioneer in mRNA technology, continues to be at the forefront of innovation in the mRNA field. Accordingly, CureVac's intellectual property rights need to be acknowledged and respected in the form of fair compensation that enables reinvestment into the advancement of mRNA technology and the ongoing development of new classes of transformative medicines.

Business Update

After three years on the CureVac management team, CureVac's Chief Business and Chief Commercial Officer, Dr. Antony Blanc, will leave CureVac at the end of his contract term on November 30, 2023. During the search for a successor, CureVac's Chief Executive Officer, Dr. Alexander Zehnder, will head the Business Development and Commercial team.

Dr. Blanc joined CureVac in 2020. His contributions were instrumental to growing and partnering the company amid the challenging pandemic environment and beyond, such as expanding the collaboration with GSK for prophylactic vaccines or the acquisition of Frame Cancer Therapeutics. The company would like to express its gratitude and wish him all the best for his next steps.

Conference call and webcast details

CureVac will host a conference call and webcast today at 3 p.m. CET / 9 a.m. ET.

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 (landline access) / 0800-184-4713 (cell phone access)

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.

Financial Update for the Third Quarter and First Nine Months of 2023

Cash Position

Cash and cash equivalents amounted to €464.1 million at the end of September 2023, decreasing from €495.8 million at the end of 2022. In the first nine months of 2023, cash used in operations was mainly allocated to payments in connection with ongoing R&D activities, for expenditures for CureVac's GMP IV manufacturing facility and the purchase of raw materials. This decrease was partially compensated by financing activities.

Revenues

Revenues amounted to €16.5 million and €31.2 million for the three and nine months ended September 30, 2023, representing an increase of €5.3 million and a decrease of €24.5 million, or 47.3% and 44.0%, from €11.2 million and €55.7 million for the same period in 2022.

The decrease over the first nine months year-on-year was primarily driven by lower revenues from the two GSK collaboration agreements as the companies agreed to focus on the larger indications. As a consequence, total GSK related revenues of €28.7 million were recognized for the nine months ending September 30, 2023, compared to €52.7 million in the prior year period. Additionally, the 2022 revenue was higher with the payment of the milestone related to starting the flu clinical trial in Panama.

Operating Result

Operating loss amounted to €54.0 million and €186.2 million for the three and nine months ended September 30, 2023, representing an increase of €1.6 million and €58.3 million from €52.4 million and €127.9 million for the same period in 2022.

The operating result was affected by several key drivers mainly related to the closing of our first-generation vaccine effort in COVID-19:

- Cost of sales decreased primarily in relation to lower write-off of raw materials. In addition, the first nine months of 2022 were impacted by additional costs related to the termination of CMO activities for the first generation COVID-19 vaccine.
- Research and development expenses increased primarily with enhanced activity in infectious disease and oncology R&D projects and development of the workforce. The first nine months of 2022 were positively impacted by €36.8 million related to the reversal of an outstanding CRO provision. Additionally, in the first nine months of 2022, Research and Development costs were positively impacted by a one-off net gain for a change in the contract termination provision resulting primarily in GSK taking over from the company committed capacity at a CMO.
- In the first nine months of 2022, other income was positively impacted by one-off compensation from GSK amounting to €32.5 million for reimbursement of prepayments and production set-up activities at a CMO.

Financial Result (Finance Income and Expenses)

Net financial result for the three and nine months ended September 30, 2023, amounted to €5.3 million and €12.7 million, or an increase of €0.6 million and €5.2 million from €4.7 million and €7.5 million for the same period in 2022. This was mainly driven by interest income on cash investments.

Pre-Tax Loss

Pre-tax loss was €48.7 million and €173.5 million for the three and nine months ended September 30, 2023, compared to €47.7 million and €120.4 million in the same period of 2022.

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 1,100 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 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, fluctuations of operating results due to the effect of exchange rates, delays in litigation proceedings, different judicial outcomes 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, 2022	September 30, 2023
Cash and Cash Equivalents	495.8	464.1

Three months ended September 30,		
(in € millions)	2022	2023
Revenue	11.2	16.5
Cost of Sales, Operating Expenses & Other	-63.6	-70.5
Operating Income		
Operating Result	-52.4	-54.0
Financial Result	4.7	5.3
Pre-Tax Loss	-47.7	-48.7

Nine months ended September 30,		
(in € millions)	2022	2023
Revenue	55.7	31.2
Cost of Sales, Operating Expenses & Other	-183.6	-217.4
Operating Income		
Operating Result	-127.9	-186.2
Financial Result	7.5	12.7
Pre-Tax Loss	-120.4	-173.5