

CureVac Announces Financial Results for the Third Quarter and First Nine Months of 2022 and Provides Business Update

- Delivering on broad second-generation vaccine development program with expansion into modified mRNA technology in collaboration with GSK
 - Phase 1 studies in influenza and COVID-19 on track to deliver clinical data in Q1 2023
- Strengthening oncology position based on preparations for new clinical studies with mRNA-based cancer vaccine candidates and positive Phase 1 data on CV8102
 - Two proof-of-principle studies planned in 2023 to validate and optimize second-generation mRNA backbone in oncology
 - Phase 1 expansion study of non-coding RNA-based candidate CV8102 confirms safety and strong immuno-modulatory characteristics
- First manufacturing licenses for The RNA Printer® in oncology expected, subject to regulatory approval; applications submitted to regulatory authorities in Q4 2022
- Driving innovation at the 10th International mRNA Health Conference with data on novel LNP delivery system and therapeutic approaches for diseases with high unmet medical need
- Cash and cash equivalents position of €540.9 million as of September 30, 2022; driven mainly by proceeds related to transfer of production capacity to GSK

TÜBINGEN, Germany/ BOSTON, USA – November 16, 2022 – 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 third quarter and first nine months of 2022 and provided a business update.

“This has been a highly productive year for CureVac, with a significant expansion of our operational bandwidth and further extension of applications for our mRNA technology,” said Franz-Werner Haas, Chief Executive Officer of CureVac. “Looking across our three core competencies, we have expanded our broad technology platform into modified as well as multivalent mRNA approaches by starting four clinical trials in COVID-19 and flu. All trials are on track to deliver important clinical data in the near future. These trials diversify and advance our product development pipeline with promising candidates, as do the new technologies fueling our growing oncology footprint and our innovations in molecular therapies. We have increased integration of our flexible and scalable manufacturing to now serve the early clinical trial stage through to commercial supply based on a unitary framework. This contributes to the speed of our product developments, further supported by our integrated end-to-end solution, The RNA Printer®, for which we have successfully filed applications for manufacturing licenses to support our oncology area.”

“In the third quarter of 2022, we further advanced our corporate transformation from a research-oriented biotech to an integrated and commercial-ready biopharma company by focusing our resources on clear priorities in our technology platform, product pipeline and manufacturing landscape,” said Pierre Kemula, Chief Financial Officer of CureVac. “For the first time since the fourth quarter of 2021, the headwind from wind-down costs related to our first-generation vaccine candidate, CVnCoV, has subsided, demonstrating our diligent work to resolve or reallocate prior commitments.”

Selected Business Updates

Prophylactic Vaccines

CureVac is delivering on its previously announced 2022 clinical development program in prophylactic vaccines and has initiated a total of four Phase 1 studies in COVID-19 and flu in collaboration with GSK. All clinical candidates are based on CureVac's second-generation mRNA backbone and are being tested as a booster vaccination. In line with the company's development strategy to take an unrestricted technology approach, each program features a candidate applying unmodified mRNA as well as a candidate applying modified mRNA to identify the best-performing candidate for later-stage clinical development.

All trials are well on track to deliver clinical data in early Q1 2023. Data are expected to be reported as combined data sets for both candidates per indication.

Oncology

Broadening of Oncology Footprint with mRNA Cancer Vaccines – Targeted Antigen Approach

CureVac continues to deliver on its previously communicated three-pillared oncology strategy, which includes validation and optimization of its broad mRNA technology approach against different classes of cancer antigens, the build-up of its pipeline of cancer vaccine candidates targeting novel antigens predicted to be highly immunogenic, and the addition of complementary platform technologies.

With the integration of novel antigen discovery technologies from the recent acquisition of Frame Cancer Therapeutics, and its partnership with immunotherapy company myNEO, CureVac is well-positioned to execute on the development of a meaningful portfolio of novel cancer vaccine candidates. Within this portfolio, CureVac is following two approaches. The first approach assesses tumor antigens shared by different cancer patients for the development of off-the-shelf cancer vaccines. The second approach is tailored to a patient's individual tumor profile.

To validate and optimize CureVac's broad mRNA technology in oncology, most notably the second-generation mRNA backbone, the company intends to start two clinical proof-of-concept studies. These studies will define the safety, immunogenicity and T cell-mediated immune activation of specific antigen-encoding mRNA cancer vaccine candidates based on the second-generation backbone. The first Phase 1 proof-of-principle study will test an mRNA construct encoding for multiple epitopes from eight tumor-associated antigens in patients with surgically resected glioblastoma. It is expected to start in the first half of 2023. The second Phase 1 proof-of-principle study will investigate an mRNA construct featuring a full-length tumor-associated antigen in solid tumors with an initial focus on melanoma patients. It is expected to start in the second half of 2023.

CV8102 – Cancer Immuno-Modulator in Solid Tumors

CureVac's non-coding RNA oncology candidate, CV8102, is being assessed in a fully recruited dose-escalation and expansion Phase 1 study to confirm safety, tolerability, and efficacy as a single agent and in combination with licensed anti-PD-1 antibodies. Preliminary results from the completed dose-escalation part of the study in a range of solid tumors were previously reported at the European Society for Medical Oncology (ESMO) conference in September 2021.

On November 11, 2022, results from the completed expansion part of the study, focusing on patients with PD-1 refractory melanoma, were presented at the Society for Immunotherapy of Cancer (SITC) conference. Preliminary efficacy was observed in patients of the anti-PD-1 combination cohort, 40% of whom were pretreated with anti-CTLA-4 antibodies. In this cohort, 17% of patients experienced a partial response. Responses appear durable for up to one year from the start of treatment. No objective responses were observed in the 10 patients of the single-agent cohort, 50% of whom were pretreated with anti-CTLA-4 antibodies.

Extensive analysis of immune cell activation to better understand CV8102-induced mobilization of the immune system against injected tumors as well as non-injected tumors confirmed, after the first dose, activation of systemic pathways of immune response. Preliminary analysis of the tumor micro-environment in a subgroup of patients showed the positive outcome of increased T cell infiltration and reduced tumor cell content in a number of analyzed paired biopsy samples. The final results are expected to be submitted for publication in a peer-reviewed journal in H1 2023.

In the context of our current strategic focus on the development of novel mRNA-based cancer vaccines, data from the planned proof-of-principle studies and parallel progress in the discovery of new tumor-specific antigens will provide the basis for any potential integration of CV8102 into this priority program as a strong immune-modulatory adjunct. Further clinical development of CV8102 will only be considered in combination with a defined mRNA cancer vaccine.

The RNA Printer® in Oncology

The RNA Printer®, CureVac's end-to-end solution for integrated and automated manufacturing of GMP-grade vaccines and therapeutics, forms an integral part of CureVac's oncology strategy. Designed for small-scale quantities, the automated output of The RNA Printer® will support the rapid and flexible provision of clinical trial material to screen and advance new antigens into clinical studies.

The system is currently undergoing regulatory approval processes to obtain its first manufacturing licenses for the mRNA constructs of the previously described planned proof-of-principle studies to support the supply of clinical trial material out of our GMP I and II facilities. The applications for the licenses were submitted to the German regional authorities in October 2022.

Presenting at the 10th International mRNA Health Conference

CureVac is committed to driving science and innovation in the field of mRNA. It presented on several lines of research at the 10th International mRNA Health Conference, the dedicated yearly meeting for mRNA science on November 8-10, 2022, in Boston, Massachusetts.

Highlights of presented preclinical studies include a new and proprietary lipid nanoparticle (LNP) mRNA delivery system as well as extended data for the previously reported study in liver fibrosis and cirrhosis.

The new LNP delivery system, which features a novel non-PEG lipid composition, was preclinically shown to provide highly localized delivery and transcription of mRNA in the immune compartment, enabling strong immune responses. A dried presentation of the new LNP was proven to be highly robust and stable at room temperature for an extended period.

A preclinical study carried out in collaboration with the REBIRTH-Research Center of the Hannover Medical School previously demonstrated restoration of hepatocyte function and inhibition of liver fibrosis and cirrhosis by HNF4A-encoding mRNA. Extended data on optimized HNF4A mRNA constructs enabled further reduction of the injected dose while triggering strong suppression of fibrogenesis.

Financial Update for the Third Quarter of 2022

Cash Position

Cash and cash equivalents were €540.9 million as of September 30, 2022, down from €811.5 million as of December 31, 2021. In the first nine months of 2022, cash used in operations was mainly allocated to payment of accounts payables, payments in connection with capital expenditures for our new production facility, purchases of materials for use in R&D and settling CMO contracts as part of the wind-down activities for our first-generation CVnCoV vaccine program; in the same period of 2021, cash used in operations was mainly allocated to prepayments to CROs and CMOs in relation to the CVnCoV program. As of September 30, 2022, CureVac has settled most of its financial obligations related to the CVnCoV program. Looking forward, we see a decrease in cash outflows relating to this program.

Revenues

Revenues amounted to €11.2 million and €55.7 million for the three and nine months ended September 30, 2022, representing a decrease of €18.1 million and €6.1 million, or a decrease of 62% and 10%, from €29.3 million and €61.8 million for the same periods in 2021.

The decrease for the nine months period ending September 30, 2022, was primarily driven by the termination of the Boehringer Ingelheim collaboration in 2021. This led to a revenue recognition of €10.0 million for the nine months ending September 30, 2021.

Revenues from the two collaborations with GSK increased year over year by €3.1 million. In the first quarter of 2022, we received a €10 million milestone payment related to the start of the seasonal influenza clinical trial. €5.8 million of this milestone was recognized pro rata as revenue in the first nine months of 2022. Under both GSK collaboration agreements, total revenues of €52.7 million were recognized for the first nine months of 2022, compared to €49.6 million in the prior year.

Operating Result

Operating loss amounted to €52.4 million and €127.9 million for the three and nine months ended September 30, 2022, representing a decrease of €90.7 million and €278.8 million from €143.1 million and €406.7 million for the same periods in 2021.

The operating result was affected by several key drivers:

- Cost of sales decreased primarily due to lower expenses for CMO services. Prior year 2021 was highly impacted by significant expenses for the set-up of a European CMO network for CVnCoV. This was partially offset in 2022 by an increase in write-off for raw materials procured to supply manufactured goods to GSK, which are now no longer expected to be used, following the transfer to GSK of reserved production capacity at a CMO.
- Research and development expenses decreased primarily due to the termination of the CVnCoV Phase 2b/3 clinical study. The first nine months of 2021 were mainly impacted by our 40,000 subject Phase 2b/3 clinical trial for CVnCoV. As of December 2021, we accrued all remaining CVnCoV clinical trial costs. With the declining number of continuing study participants and re-negotiation of contracts in the first nine months of 2022, our remaining clinical trial costs estimate decreased, resulting in the reversal of €36.8 million of the provision recorded as of December 2021.

Additionally, research and development costs were positively impacted by a net gain from a change in the estimate in the contract termination provision, resulting primarily from the transfer of committed capacity at a CMO to GSK in the first quarter of 2022.

- Other income decreased but was positively impacted by €32.5 million in compensation from GSK for the reimbursement 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 German Federal Ministry of Education and Research, or BMBF.

Financial Result (Finance Income and Expenses)

Net financial result for the three and nine months ended September 30, 2022, was positive with €4.7 million and €7.5 million, respectively, representing an increase of €5.1 million and €8.7 million from a loss of €0.4 million and €1.2 million for the same periods in 2021. Financial result for the nine months ended September 30, 2022, was driven by foreign exchange gains and interests on cash investments.

Pre-Tax Loss

Pre-tax loss was €47.7 million and €120.4 million for the three and nine months ended September 30, 2022, compared to €143.5 million and €407.9 million in the same respective periods of 2021.

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 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, 2021 (audited)	September 30, 2022 (unaudited)
Cash and Cash Equivalents	811.5	540.9

(in € millions)	Three months ended September 30,	
	2021 (unaudited)	2022 (unaudited)
Revenue	29.3	11.2
Cost of Sales, Operating Expenses & Other Operating Income	-172.4	-63.6
Operating Result	-143.1	-52.4
Financial Result	-0.4	4.7
Pre-Tax Loss	-143.5	-47.7

(in € millions)	Nine months ended September 30,	
	2021 (unaudited)	2022 (unaudited)
Revenue	61.8	55.7
Cost of Sales, Operating Expenses & Other Operating Income	-468.5	-183.6
Operating Result	-406.7	-127.9
Financial Result	-1.2	7.5
Pre-Tax Loss	-407.9	-120.4