

CureVac Conference Call, November 14, 2023

# Third Quarter and First Nine Months 2023 Financial Results and Business Updates

#### **Presenters**

Dr. Alexander Zehnder Chief Executive Officer

Dr. Myriam Mendila Chief Development Officer

Pierre Kemula Chief Financial Officer

Dr. Sarah Fakih Vice President Corporate Communications &

**Investor Relations** 

For the Q&A session:

Marcus Dalton Head of Intellectual Property

# **SARAH FAKIH**

Thank you. Good morning, good afternoon and welcome to our conference call. My name is Sarah Fakih, and I'm the Vice President of Corporate Communications and Investor Relations at CureVac.

Please let me introduce today's speakers.

On the call with me from CureVac are Alexander Zehnder, Chief Executive Officer of CureVac; Myriam Mendila, our Chief Development Officer; and Pierre Kemula, Chief Financial Officer of CureVac. Our Head of Intellectual Property, Marcus Dalton, will be present for the Q&A Session.

Please note that this call is being webcast live and will be archived on the Events and Presentations section under Investor Relations on our website.

Before we begin, a few forward-looking statements. The discussion and responses to your questions on this call reflect management's view as of today, Tuesday, November 14, 2023. We will be making statements and providing responses to your questions that state our intentions, beliefs, expectations or predictions of the future. These constitute forward-looking statements for the purpose of the safe harbor provisions. These statements involve risks and uncertainties that could cause actual results to differ, materially, from those projected.

CureVac disclaims any intention or obligation to revise any forward-looking statements. For more information, please refer to our filings with the U.S. Securities and Exchange Commission.

I will now turn the call over to Alexander.

#### **ALEXANDER ZEHNDER**

Thank you, Sarah. Ladies and gentlemen, good morning, good afternoon to everybody on the webcast.

As another year of strong performance draws to a close, we continue to successfully maintain our forward momentum in the clinical development programs in infectious diseases as well as in oncology.

We are delivering across our strategic priorities.

Our lead programs in COVID-19 and seasonal flu, jointly developed with GSK, are now in Phase 2 and on track for delivering interim topline data in 2024.

The Phase 2 COVID-19 study recently completed enrollment and we expect interim data early next year.

In the Phase 2 part of the combined Phase 1/2 study for seasonal flu, the first participant was dosed, and we expect interim Phase 2 data in 2024.

In oncology, our Phase 1 study in patients with resected glioblastoma is advancing and has recently progressed to the opening of the third dose level in the initial dose-escalation part of the study. We continue to expect data in the second half of 2024.

We supported this Phase 1 study with promising data from a preclinical study that we presented at the beginning of this month at the 11th mRNA Health Conference, which CureVac hosted in Berlin, and which is a global flagship mRNA R&D event.

Also supporting our oncology strategy is The mRNA Printer®, CureVac's end-to-end solution for integrated and automated manufacturing of GMP-grade mRNA vaccines and therapeutics. The printer achieved an initial regulatory milestone by obtaining its first manufacturing license for an mRNA cancer vaccine candidate. The regulatory review process is ongoing to provide greater freedom and flexibility to manufacture different mRNA cancer vaccine candidates.

Considering our current cash runway, our efforts in advancing our clinical development programs continue to be supported by prudent fiscal discipline. Our cash position of 464.1 million U.S. dollars at the end of the third quarter provides a solid basis to continue to execute on our programs and priorities until mid-2025.

As the pioneering company in mRNA technology, having maintained a tradition of scientific leadership for more than two decades, CureVac continues to defend a broad and diversified intellectual property portfolio.

Our litigation against Pfizer/BioNTech in Germany and in the U.S. has progressed, with favorable developments in the German court and the provision of a trial date in the U.S. on October first, 2024.

Please let me remind you, that in an industry where innovation is a key driver of value, patent disputes are commonplace.

In all currently pending cases, our interest is solely in having our intellectual property rights acknowledged and fairly compensated, so that all parties can continue advancing new transformative mRNA-based medicines.

On slide 5, we show the CureVac product development pipeline, which forms the core of our business strategy. The pipeline leverages our unique platform in the three therapeutic areas of prophylactic vaccines, oncology and molecular therapy.

In our most advanced area, prophylactic vaccines, we now have two programs in Phase 2, which are driven by our clinically validated technology platform and proprietary second-generation mRNA backbone.

Our Phase 2 COVID-19 and seasonal flu vaccine candidates are developed in collaboration with GSK. The two Phase 1 studies we started in each indication last year to identify the best mRNA technology have successfully evolved into the two current Phase 2 studies testing updated candidates.

We continue to translate the insights from our clinical infectious disease studies into our oncology area. Our proof-of-concept Phase 1 study in patients with resected glioblastoma is well on track, as previously mentioned. Combined with our highly differentiated capabilities in tumor antigen discovery, the study will be an important basis to further optimize our mRNA backbone to provide differentiated cancer vaccine candidates.

In the third therapeutic area, molecular therapy, we are developing optimized mRNA therapeutics, together with several collaboration partners, which are intended to enable the expression of therapeutic proteins to treat rare and metabolic diseases.

We are continuously investing in our development pipeline to advance innovation in health solutions for people and patients.

With this let me hand over to Myriam for an update on our clinical development programs.

# **MYRIAM MENDILA**

Thank you, Alexander.

I am now on slide 6 to give you an overview of our two most advanced clinical vaccine development programs, in COVID-19 and seasonal flu, jointly being developed with GSK.

As Alexander already mentioned, we recently reported solid progress in both programs, with the completion of enrollment in the ongoing COVID-19 Phase 2 study and dosing of the first participant in the Phase 2 part of the combined Phase 1/2 study in seasonal flu.

In the Phase 2 COVID-19 study shown on the left-hand side of the slide, we assess the safety and immunogenicity of different single booster doses of two vaccine candidates based on our proprietary second-generation mRNA backbone.

The first candidate, CV0601, is a modified, monovalent construct encoding the Omicron BA. 4-5 variant. The second candidate, CV0701, is a modified, bivalent construct encoding the Omicron BA. 4-5 variant as well as the original SARS-CoV-2 strain.

According to the applicable and available standard-of-care, when the first participant of the Phase 2 COVID-19 study was dosed in early August 2023, the study employs a licensed bivalent mRNA vaccine as a comparator.

We expect interim Phase 2 data early next year, which will inform the design of a pivotal Phase 3 study planned to start in 2024. Following the September update of the COVID-19 standard-of-care in the U.S., the planned Phase 3 study is expected to feature an updated vaccine candidate and updated comparator vaccine according to the latest requirements.

The Phase 1/2 study for seasonal flu is shown on the right-hand side of the slide. In this study, we are assessing the safety, reactogenicity and immunogenicity of flu vaccine candidates compared to licensed comparator vaccines. The Phase 1 dose-escalation part has already completed initial data analysis. It tested a comprehensive series of multivalent, modified mRNA seasonal flu candidates with up to eight mRNA constructs per candidate at different dose levels in 270 healthy younger adults.

Interim Phase 1 safety data showed no safety concerns across all tested dose levels. The observed antibody responses supported the selection of a preferred vaccine candidate, which has now been advanced to the Phase 2 part of the study. The potentially differentiated, multivalent candidate encodes antigens that address all four WHO-recommended flu strains.

It will be tested in both healthy younger and older adults at different dose levels and will be compared to two different licensed seasonal flu comparator vaccines with intended use for the respective age group. Interim data are expected in 2024.

Let us take a closer look at the study design of the two ongoing Phase 2 studies in COVID-19 and seasonal flu on slide 7.

While we don't disclose the exact dose levels for both studies, the COVID-19 Phase 2 study features a medium dose framed by a higher and lower dose for the bivalent candidate CV0701 and a medium dose level for the monovalent candidate CV0601. All dose levels, including the licensed bivalent mRNA comparator vaccine, are fully recruited with a total of 427 participants aged 18 years and older.

For seasonal flu, the selected multivalent candidate is being tested in two separate age groups: 480 younger adults, aged 18 to 64, and 480 older adults aged, 65 to 85. Each age group features three different dose levels of the candidate as well as the age-appropriate licensed comparator vaccine.

With this, let me now shift gears and turn to our development progress in the oncology area.

On slide 8, I would like to provide a more detailed overview of the ongoing Phase 1 study we are currently conducting in patients with surgically resected MGMT unmethylated glioblastoma.

On the left-hand side of the slide, you can see the schematic setup of the applied cancer vaccine candidate CVGBM, with a focus on its coding region. The candidate is based on our advanced second-generation mRNA backbone and features a single unmodified mRNA. It encodes eight epitopes derived from tumor-associated antigens with demonstrated immunogenicity in glioblastoma. The exact nature of the epitopes is not being disclosed; however, you can see that CVGBM encodes five MHC class one epitopes and three MHC class two epitopes.

MHC complexes of both classes are expressed on immune and other cells and present antigens, including tumor antigens, to initiate CD8 and CD4 T cell responses against those antigens. CVGBM utilize this concept to activate CD8 and CD4 T cells for an optimal anti-tumor response. We clinically assess this vaccine design in the open-label Phase 1 study, which is described in more detail on the right-hand side of the slide.

The study evaluates the safety and tolerability of CVGBM in two parts – the currently ongoing dose-escalation part A is expected to enroll up to 24 patients and a subsequent dose-expansion part B will include approximately 20 patients. In the dose-escalation part, four core dose levels between 12 and 100 micrograms are being tested. The first three dose levels have successfully been opened and recruitment is progressing without dose limiting toxicities to date.

The trial is being conducted in Germany, Belgium and the Netherlands. A first data read-out is expected in the second half of 2024.

In this context, on slide 9, I would like to highlight the results of a preclinical study that we presented two weeks ago at the 11th International mRNA Health Conference, hosted by CureVac in Berlin.

We conducted this extensive study in mice to assess the potential of the multiepitope mRNA design we applied for our clinical candidate CVGBM. The study assessed a multiepitope mRNA design encoding ten separate epitopes derived from the B16.F10 melanoma cell line, a well-known melanoma cancer model in mice.

Similar to glioblastoma, the B16.F10 melanoma grows very aggressively due to an immune-suppressive tumor microenvironment. The resulting tumors are poorly immunogenic, so-called "cold" tumors, which are cytokine-deficient and exhibit only very little T cell infiltration. Accordingly, the tumor model is known to be resistant to check-point inhibitors and cannot be addressed with a PD-1 blocking antibody monotherapy.

We are therefore all the more pleased that the immunogenicity data obtained on Day 21, illustrated on the left side of the slide, demonstrates prominent induction of CD8 T cell responses against five and CD4 T cell responses against two of the encoded epitopes.

In B16.F10 tumor-bearing mice, the successful induction of solid T cell responses against the tumor antigens led to a significantly extended median survival by approximately 50 percent for treated mice compared to mice vaccinated with a formulated control mRNA.

The preclinical data suggest that the monotherapy regimen with our multiepitope mRNA construct was able to efficiently recruit T cells to this challenging tumor microenvironment, thereby inhibiting tumor growth and extending animal survival.

With this let me hand back the call to Alexander.

# **ALEXANDER ZEHNDER**

Thank you, Myriam.

To finalize our oncology update, The RNA Printer®, our highly automated solution for GMP-grade manufacturing of cancer vaccines, has achieved its first regulatory milestone. The printer obtained its first manufacturing license for a defined mRNA construct to support our oncology strategy. The first license was granted for the manufacturing of the therapeutic mRNA by the DNA- and mRNA-modules of the printer.

Subject to ongoing regulatory review, we aim the license to be expanded to a framework license, which will allow the flexible manufacturing of different mRNA constructs based on the established processes. In 2024, our goal is to further expand this approach to also include the formulation module of the printer to complete the end-to-end capabilities of the system.

Let me now address on the next few slides a topic that has gained in attention in 2023 – namely our broad and diversified intellectual property portfolio.

Over these next few slides, I would like to address the background of the ongoing legal action in Germany and the U.S. by laying out the intellectual property rights in both jurisdictions, the innovations they refer to, the responsible courts and timelines as well as upcoming milestones.

Let us start by looking at Germany, where the process is generally more complex compared to the U.S.

On the left-hand side of slide 11, you can see that there are a total of eight intellectual property rights at issue in Germany, which can be divided into three patents and five utility models. Utility models don't have an equivalent in the U.S. but are available in different countries, including Germany. They represent a class of intellectual property rights which, unlike a patent, is not subject to an examination and therefore does not have an initial presumption of validity. Correspondingly, a utility model is registered rather than granted.

However, utility models are much faster to obtain than patents. They offer the same protection as patents, but their term is limited to 10 years. A claim to damages – if validity is confirmed in associated proceedings – will be awarded in the same way as for a patent.

Patent protection normally evolves alongside a multi-year product development. In the case of COVID-19, we chose to file utility models as speed was critical to protect our innovations in the unprecedented dynamic mRNA field generated by the pandemic.

On the right-hand side of the slide, the eight IP rights are sorted by patent family. The first two patent families cover foundational inventions to improve mRNA stability for medical use. These include enrichment of the G/C content of the mRNA molecule and implementation of a split poly-A tail.

The third patent family covers inventions that were specific to the development of prophylactic vaccines against SARS-CoV-2.

Under German law, the courts that determine IP infringement are separate from the authorities that decide on IP validity. This means infringement and validity cases often proceed in parallel, with damages assessed only when infringement and validity have been established.

On slide 12, you can see a schematic of this bifurcated German process. The upper stream represents the infringement proceedings that would lead to a subsequent damages trial.

For our IP dispute, infringement as well as potential damages related to all eight IP rights is initially decided by the Regional Court Düsseldorf. The lower stream represents validity proceedings. Validity of our IP rights is heard by different authorities depending on the nature of the IP right.

# This includes

- the European Patent Office for the split poly-A tail patents
- the German Federal Patent Court for the G/C enrichment patent, and
- the German Patent and Trademark Office for all five utility models

I would like to draw attention to the fact that this two-stream setup applies to each of the eight IP rights at issue in Germany. Each IP right is handled as a separate case for which infringement, validity and potential damages will be decided separately.

This provides us multiple opportunities in our German proceedings to have some aspect of our intellectual property rights acknowledged and fairly compensated.

On slide 13, you can see a timeline overview of the infringement as well as validity proceedings in terms of past as well as upcoming milestones in 2023 and 2024. The part above the timeline references infringement milestones, the part below validity milestones.

Looking at the validity proceedings on the bottom part of the slide, you can see that on April 6, 2023, the German Federal Patent Court issued a positive preliminary opinion on the G/C enrichment patent, supporting its validity. At the same time, the court set an oral hearing for December 19, 2023, where we expect a ruling on the validity of the patent.

Looking at infringement proceedings at the top part of the slide, a public hearing on the first five IP rights took place on August 15, 2023, before the Regional Court Düsseldorf. At this hearing, the court announced that on December 28, 2023, a ruling on infringement of the G/C enrichment patent will be given.

This means that the G/C enrichment patent will be the first IP right for which both validity and infringement are decided, and that December 2023 will be the first major milestone in our German litigation.

For the remaining four rights under consideration from the August 15 hearing, infringement proceedings continued until September 28, when the court in Düsseldorf postponed an infringement ruling on those remaining four rights until their validity challenges have been resolved by the respective authorities. Let me explain why we consider the postponement a favorable outcome for CureVac.

German infringement courts typically delay their proceedings to wait for a decision on validity only in cases where they consider the challenged intellectual property right to be infringed. Therefore, it can be inferred that the Regional Court Düsseldorf considers all four intellectual property rights infringed. The court noted that the questions of validity still needed to be determined. Accordingly, it decided to postpone the infringement proceedings until the validity of these four IP rights has been assessed.

The postponement does not reflect a preliminary assessment by the Düsseldorf court of validity. Validity can only be determined by authorities that are technically qualified and specialized in validity cases.

Moving on to the litigation in the U.S., again, on the left-hand side of slide 14, you can see that there is a total of ten U.S. patents currently at issue.

These patents cluster into four families, which mostly relate to the same innovations already discussed for the Germany litigation, namely the stabilization of mRNA via G/C enrichment and implementation of a split poly-A tail as well as the design of SARS-CoV-2 specific vaccines. An additional patent family added in the U.S. relates to the innovation of filtration-based mRNA purification methods, which forms a critical part of the overall mRNA manufacturing process.

Looking at the litigation timelines and milestones in the U.S. on slide 15, the picture is more straightforward and a lot less complex compared to Germany. For a start, all proceedings, including validity, infringement and potential damages are public and heard by the same court. Also, all three proceedings will be decided in one trial and this trial will cover all ten patents. Therefore, there is no differentiation between proceedings featured in this timeline overview.

As a brief reminder, the U.S. litigation was initiated with a Declarative Judgement Action filed by Pfizer/BioNTech in July 2022 in the federal district court of Massachusetts, seeking confirmation that Comirnaty® does not infringe three CureVac patents.

In May 2023, we successfully transferred the case to the U.S. District Court for the Eastern District of Virginia, followed by our counter claim alleging infringement of six additional patents, which were further extended by another patent in July 2023 to result in the overall ten patents litigated now.

The District Court for the Eastern District of Viriginia is well-known to have one of the fastest trial dockets in the U.S. Accordingly, a trial date has already been set for October first, 2024.

We remain confident in the strength of our IP portfolio and continue to make progress toward the recognition of our pioneering contributions to the development of COVID-19 mRNA vaccines.

With this I would like to conclude the business update and hand over to Pierre for a review of the financial data.

# **PIERRE KEMULA**

Thank you, Alexander and good morning, good afternoon to everyone on the call.

Looking at our cash position on slide 16, as already mentioned, we closed the third quarter and first nine months of 2023 with 464.1 million euros.

Cash used in operations was mainly allocated to R&D activities, expenditures for our GMP IV production facility and purchases of R&D materials. I will underline in this presentation the significant one-off effects that took place in 2022 as a consequence of closing our first-generation vaccine efforts in COVID-19.

But first, let us look at Revenues. Revenues increased by 5.3 million euros to 16.5 million euros for the third quarter and decreased by 24.5 million euros to 31.2 million euros for the first nine months of 2023, compared to the same periods in 2022. The decrease over the first nine months year-on-year was primarily driven by lower revenues from our two GSK collaboration agreements. Revenues from both collaborations decreased year-on-year and amounted to a total of 28.7 million euros in the first nine months of 2023 compared to 52.7 million euros in the same period in 2022. The decrease was driven by two elements:

- First, the agreement of both companies to focus on the larger indications.
- Second, a higher 2022 comparator base due to the recognition of the milestone related to the start of the flu Phase 1 clinical trial in Panama.

Operating loss was 54.0 million euros for the third quarter of 2023, representing a 1.6-million-euro-increase compared to the same quarter of 2022.

For the first nine months of 2023, operating loss increased by 58.3 to 186.2 million euros compared to the same period in 2022.

The operating result was affected by several key drivers:

- First, cost of sales decreased year-on-year, mainly as the impact of our first-generation COVID-19 vaccine subsided. This resulted in lower write-off of raw materials in the first nine months of 2023 as well as lower impact on costs related to the termination of CMO activities.
- Second, R&D expenses increased with higher investments in later-stage infectious disease and oncology development programs, as well as strengthening of the workforce.
  - In the first nine months of 2022, R&D expenses were positively impacted by 36.8 million euros related to the reversal of an outstanding CRO provision as well as 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.
- Third, and still in the first nine months of 2022, other income was positively impacted by a one-off 32.5 million euros for reimbursement of pre-payments and production activity set-up at a CMO.

Financial results increased by 0.6 million euros to a profit of 5.3 million euros in the third quarter of 2023 and increased by 5.2 million euros to a profit of 12.7 million euros for the first nine months of 2023, compared to the same periods in 2022. They were mainly driven by interest income on cash investments.

Pre-tax losses were 48.7 million euros for the third quarter and 173.5 million euros for the first nine months of 2023.

With this I would like to hand back the call to Alexander for a summary today's key messages.

# **ALEXANDER ZEHNDER**

Thank you, Pierre.

The key take-away message today is that we continue to deliver across our strategic priorities in 2023 by successfully advancing our clinical lead programs in infectious diseases and oncology.

Our Phase 2 studies in COVID-19 and seasonal flu, which are being conducted in collaboration with GSK, as well as our Phase 1 study in glioblastoma are progressing according to plan. We

expect to maintain our strong momentum in 2024 with clinical key data from all three studies as well as the expected advancement to Phase 3 developments in infectious diseases.

Together with the progress we have made in safeguarding our investment in innovation and our strong cash position of 464.1 million euros, which will support the execution on our priorities through mid-2025, this clinical progress underscores our strong commitment to introduce new healthcare solutions to the market.

With this I would like to conclude our presentation and would now open the webcast to your questions.

# **SARAH FAKIH**

With this, we would like to conclude this conference call. Thank you very much for your participation. Stay safe, and please don't hesitate to contact us should you have any further questions.

Thank you, and goodbye.