CureVac Conference Call, November 19, 2021

Third Quarter and First Nine Months 2021 Financial Results and Business Updates

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Presenters

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Dr. Mariola Fotin-Mleczek	Chief Technology Officer (Q&A Availability)
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SARAH 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 Franz-Werner Haas, the Chief Executive Officer of CureVac, Klaus Edvardsen, our Chief Development Officer and Pierre Kemula, Chief Financial Officer of CureVac. Mariola Fotin-Mleczek, our Chief Technology Officer will be available for the Q and 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, Friday, November 19, 2021.

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 Franz.

FRANZ Thank you Sarah. Ladies and gentlemen, a warm welcome to this conference call from all of us here at CureVac.

Let me begin with a brief assessment of where we stand today. The global fight against SARS-CoV-2 continues and while licensed vaccines have helped to manage initial large-scale vaccination programs, the world still needs additional and improved vaccines to allow for broader vaccination coverage, more differentiated protection and simplified delivery logistics to control the virus in the long term.

Recognizing this changing situation, our decisions made during the third quarter of 2021 have positioned CureVac well to develop vaccines that are expected to meet these goals.

Let me give you a short overview of selected key developments in the third quarter.

In October this year, we made the strategic decision to withdraw our first-generation COVID-19 vaccine candidate, CVnCoV, from regulatory review based on a combination of factors that included potential overlap with timelines for a second-generation candidate and the changing need towards differentiated vaccines.

We made this decision because we remain committed to the long-term fight against COVID-19 and – together with our partner GSK – have decided to be fast with a second-generation vaccine rather than late with an age-restricted first-generation product.

The first candidate from our jointly developed COVID-19 second-generation program, CV2CoV, is an unmodified mRNA construct that has shown great potential in several preclinical models.

Comprehensive preclinical data in non-human primates show that CV2CoV outperforms our first-generation candidate in every tested parameter. This data was recently complemented by a direct comparison of CV2CoV with the commercially available Pfizer/BioNtech vaccine, showing that CV2CoV is able to induce highly comparable neutralizing antibody titers in non-human primates.

The full comparison data was published in Nature yesterday, providing substantiated support of the unmodified mRNA approach for the entire field of mRNA technology, and Klaus will update you on our technology approach in our second-generation vaccine program later.

In oncology, we recently presented updated Phase 1 data of our lead candidate, CV8102, at SITC. Deep analyses of immune cell activation in blood samples and tumor biopsies supported a mechanism by which CV8102 induces immune responses throughout the entire body to fight tumors that are directly injected with CV8102 as well as distant non-injected tumors.

In our third therapeutic area, protein therapy, or as we recently renamed it, molecular therapy, we recently published preclinical data in the Journal of Hepatology. The data provide the first experimental proof that an mRNA therapeutic can serve as potential treatment option for liver fibrosis – showing the potential of the technology in this challenging area.

Beyond the mRNA technology platform, we are also advancing our manufacturing technologies, adjusting our capacity needs to the anticipated volume of second-generation vaccines in COVID-19 and other infectious diseases.

On the financial side, we closed the third quarter of 2021 with a favorable cash position of 1.06 billion euros.

Subject to market conditions, we may conduct in the future at-the-market offerings to sell shares worth up to 600 million US-dollars. Applying this facility will potentially provide additional means to accelerate the development of the company as well as our technology across our therapeutic areas.

Before we go into the detail of these program updates, I would like to take a step back and provide a look at the CureVac pipeline and the areas and diverse indications where we apply RNA technology to address diseases with a high unmet medical need.

We have said it many times before but please let me repeat: the era of RNA technology has only just begun. While mRNA was validated as a key technology in the fight against COVID-19, its potential extends to a much broader range of medical indications – in prophylactic vaccines and beyond.

Correspondingly, the CureVac pipeline builds on three main therapeutic areas: Prophylactic vaccines, oncology and molecular therapy.

Following the withdrawal of our first-generation vaccine candidate, CVnCoV, our prophylactic vaccine pipeline is led by the broad second-generation infectious disease program, including COVID-19, developed in collaboration with GSK.

The program applies an unrestricted technology approach, investigating both unmodified as well as modified mRNA constructs.

As already mentioned, the first representative of the second-generation COVID-19 program is CV2CoV, an unmodified mRNA, which has pre-clinically shown significantly improved immune responses compared to our first-generation candidate, matching neutralizing antibody titers of the Pfizer/BioNtech vaccine, Comirnaty®, in a direct comparison.

In the broader infectious disease program, the first non-COVID representative is an influenza vaccine. First constructs are currently being assessed in preclinical models and a clinical study is expected to start in the first half of 2022.

There is clear translation of COVID-19 learnings for immuno-oncology, where the same principles are applied to induce a strong systemic and tumor-directed immune response.

In oncology, we are exploring a range of different approaches. Our lead candidate CV8102, is currently being assessed in a Phase 1 clinical trial in solid tumors.

We are also evaluating approaches to novel cancer vaccines targeting shared neo-antigens and tumor associated antigens.

In the third therapeutic area, molecular therapy, we are developing optimized mRNA therapeutics together with a number of renowned collaboration partners for the development of antibodies or therapeutic proteins intended to treat diseases characterized by missing or inactive proteins.

Let me now hand over the call to Klaus to walk you through the details of our program updates.

KLAUS Thank you Franz. On slide 6, I would like to start with our prophylactic vaccines area. Let me briefly remind you of the scope of our broad infectious disease collaboration with GSK, in which we are jointly developing a suite of potentially improved second-generation vaccine candidates for COVID-19 as well as for a broad range of other infectious diseases.

Our second-generation vaccines are based on an advanced mRNA setup featuring targeted optimization to the untranslated regions of the mRNA to enable improved translation and extended protein expression for stronger and earlier immune responses.

Due to the need for more differentiated vaccines in the ongoing fight against COVID-19, these characteristics will be key to developing advanced vaccine candidates that also feature multivalent formats for simultaneous protection against different COVID-19 variants or for a combination of different infectious diseases, such as COVID and flu.

As Franz highlighted before, this includes an extension of our technology platform to modified mRNA constructs to allow for data-driven selection of the best possible candidates.

With CV2CoV, we have pre-clinically advanced the first representative of a large second-generation COVID-19 program, which I will speak about in more detail on the coming slides.

We aim to kick-off the second-generation COVID-19 clinical development program within the next few months and intend to also explore modified constructs within the trial.

On the infectious disease side, our jointly developed flu construct is currently in pre-clinical testing and will enter the clinic in the first half 2022.

Let me now briefly go into the preclinical data of CV2CoV, demonstrating the strong potential of our second-generation mRNA setup.

The data shown on slide 7 represent an excerpt from a large preclinical dataset in non-human primates, generated in collaboration with Harvard Medical School, published online in Nature yesterday.

The preclinical study, initially uploaded to the bioRxiv preprint server, features a direct comparison of CV2CoV and CVnCoV fully immunized animals.

In the study, CV2CoV exhibits significantly improved neutralizing antibody levels compared to CVnCoV, which range about 50 times higher one week after second vaccination. Faster onset of neutralizing antibodies led to meaningful titers just two weeks after the first vaccination, seven times higher when compared to CVnCoV which was still at baseline.

Consistently higher antibody titers for CV2CoV were also observed in response to relevant COVID-19 variants, including the Delta variant.

We recently extended the comparison data in non-human primates by a direct comparison of CV2CoV with the licensed Pfizer/BioNtech vaccine, Comirnaty®.

Neutralizing antibody titers were measured following full vaccination of animals with either 12 micrograms of CV2CoV or the standard dose of 30 micrograms of Comirnaty®. At peak immunity at week five, neutralizing antibody titers induced by CV2CoV were highly comparable to titers induced by the licensed vaccine.

In summary, the CV2CoV data demonstrate how targeted optimization of a non-chemically modified mRNA construct can substantially improve immunogenicity in preclinical studies.

The data thereby demonstrate the overall relevance of the unmodified approach for our understanding of the potential of mRNA technology as a whole.

Moving on to the oncology part of our pipeline on slide 9, I would like to update you on the progress of our lead candidate, CV8102, currently under evaluation in a Phase 1 clinical trial.

Let me briefly remind you that CV8102 is a non-coding RNA optimized to activate RNA receptors that normally detect viruses, including toll-like receptors 7 and 8 as well as RIG-one. When injected directly into the tumor, CV8102 mimics a viral infection of the tumor which can activate the immune system to reject the tumor.

It is hypothesized that the locally induced immune response in the injected tumor is amplified throughout the body based on the release of tumor antigens and the activation of tumor-specific T cells that are able to kill tumor cells at the injected site, but also at distant non-injected tumors or metastases.

The Phase 1 clinical trial is evaluating administration of CV8102 in patients with advanced melanoma, squamous cell carcinoma of the skin and head and neck, or adenoid cystic carcinoma. Patients receive CV8102 as single agent or in combination with anti-PD-1 therapy.

The trial is a two-part study. A dose-escalation part has already been completed. An expansion part of the study – initiated in February this year – specifically evaluates CV8102 in 40 additional patients with advanced melanoma.

On slide 10, you can see the latest update on CV8102 efficacy from the dose-escalation part of the study. The data represent a cut-off date from June this year and were presented at the ESMO conference in September.

On the left, evidence of single-agent activity can be observed in one patient with a complete response and one patient with a partial response in melanoma as well as one patient with a partial response in cutaneous squamous cell carcinoma. Overall, twelve patients experienced a stabilization of disease, including shrinkage of non-injected lesions in some patients.

The combination group on the right includes more heavily pretreated patients who were indicated for anti-PD-1 therapy or who did not respond or slowly progressed on anti-PD-1 therapy.

So far, two melanoma patients could be observed with a partial response and two further melanoma patients experienced stable disease as well as one patient with head and neck cancer.

At the SITC conference last week we presented additional detailed immune profiling data from the CV8102 Phase 1 dose-escalation part. The data is based on blood samples from all patients as well as tumor biopsies of injected and non-injected tumors from four patients.

The data support the hypothesis that the local injection of CV8102 into a single tumor is able to induce a systemic response leading to an immune attack against both injected and non-injected tumors.

Tumor biopsy data confirmed strongly increased T cell infiltration by both CD4 and CD8 T cells and a corresponding decrease of the tumor cell content. Blood samples of patients in all dose groups further confirmed broad activation of the innate immune system within 24 hours after injection, mainly characterized by interferon-alpha and interferon-gamma.

In the expansion part of the Phase 1 study patient enrollment was completed in October. Data, including biopsies from over 20 patients, is expected to be reported in the second half of 2022 and will further complement our understanding of the therapeutic effect of CV8102.

On slide 12 let me now transition to the third therapeutic area of our pipeline: Protein Therapy, or as we have more accurately renamed it – Molecular Therapy.

As Franz has already highlighted, our development efforts in Molecular Therapy target diseases characterized by missing or inactive proteins to provide optimized mRNAs that can restore or replace these proteins.

In this area, we recently published promising preclinical mouse data in liver fibrosis, a disease that contributes to millions of deaths annually. The study was carried out in collaboration with the REBIRTH-Research Center at the Hannover Medical School. Progression of liver fibrosis is associated with a gradual decrease of HNF4A – a protein essential for liver development and metabolism.

The data shown on the left illustrate reduced HNF4A levels in fibrotic versus healthy mice.

To circumvent this decrease, we developed an optimized mRNA encoding for HNF4A that was able to induce production of the missing protein inside cells – as shown in the middle graph.

Correspondingly, administration of HNF4A mRNA to fibrotic animals was indeed able to restore HNF4A levels and significantly reduce liver injury. This is illustrated on the right by the reduction of ALT, an indicator of liver damage.

Overall, the study demonstrates the potential of mRNA technology in molecular therapies and provides the first experimental proof that mRNA therapeutics can serve as a potential treatment option for liver fibrosis.

With this, let me hand the call back to Franz.

Franz Thank you Klaus. I am now on slide 13 to give you an overview of the current plans for our manufacturing capacities.

We are continuously adjusting our capacity projections to ensure that we can rapidly and flexibly deliver potential second-generation vaccines in line with the anticipated volumes.

The switch of the manufacturing setup from the production of first- to second-generation constructs at our in-house plant GMP III and the facilities of our European network partners is progressing.

This includes the implementation of processes for flexible adaption to new, variant-specific constructs as well as processes for the production of modified mRNA constructs, which we explore as part of the second-generation development program.
For CV2CoV, we have already produced material for the upcoming Phase 1 clinical trial in our in-house plants, GMP I and II.

The build-up of our commercial-scale manufacturing plant GMPIV is also progressing as planned, representing an important factor in our setup to efficiently deliver on future public health needs and pandemic preparedness initiatives.

Now let me hand over to Pierre for a review of the financial data.

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

We are successfully progressing in the transition from our first to second-generation vaccine program while executing on our financial strategy.

We have set up an at-the-market financing in September this year, which, subject to market conditions, may provide us the option to offer in the future shares worth up to 600 million dollars over a period of several years.

If we are able to use the at-the-market tool in the future, we expect to use the proceeds to provide further means to fund the transition from first to second-generation vaccines as well as accelerate the momentum of our RNA technology across our therapeutic areas.

Before we go into the cash and P&L discussion on slide 15, let me briefly update you on the anticipated financial impact of withdrawing CVnCoV from regulatory review, with a focus on the Advanced Purchase Agreement – or APA – with the European Commission signed in November 2020.

The European Commission and CureVac had structured the APA to share the financial risk of our accelerated efforts to develop a safe and efficacious vaccine by providing a 450 million euros upfront payment. According to the EU APA, we must only return the unspent amount of the prepayment and we are in the process of submitting to the European Commission a report of expenses or expenses committed to using the upfront payment.

At this stage, we do not expect that we will be required to return any portion of it.

The value of certain assets, semi-finished and finished goods that will have no future use will be assessed in the fourth quarter of 2021.

We are currently coordinating with the European Commission to evaluate whether it will exercise its option to recover some raw materials and or primary components paid for with the upfront as allowed for under the APA.

With that let me resume the financial review. Looking at our current cash position, we closed the third quarter of 2021 with a favorable cash position of 1.06 billion euros.

Over the first nine months of 2021, the development of our cash position was mainly driven by raising 404 million euros in net proceeds from our follow-on financing in Q1 2021, a 75 million euro upfront payment following our collaboration extension with GSK and a 38.3 million euro tranche from the grant from the German Federal Ministry of Education and Research. Cash was used mainly for the development of CVnCoV.

Moving on to our Profit and Loss statement, revenues increased 24.1 million euros to 29.3 million euros for the third quarter of 2021 and 19.0 million euros to 61.8 million euros for the first nine months of 2021, compared to the same periods in 2020.

The increase was mainly driven by revenues from our GSK collaboration, which provided 49.6 million euros in revenues in the first nine months of 2021. In addition, termination of the Boehringer Ingelheim collaboration agreement for our legacy clinical candidate in non-small cell lung cancer became effective on November 17, 2021. The remaining contract liability, related to the upfront payment, is now fully recognized. For the first nine months of 2021, this led to 10.0 million euros being recognized as revenue compared to 1.4 million euros in 2020.

These increases were partly offset by a 33.1 million euro one-time effect in the second quarter of 2020.

Operating loss was 143.1 million euros for the third quarter, representing a 106.4-million-euro increase compared to the same period in 2020.

For the first nine months operating loss increased by 343.5 million euros to an overall 406.7 million euros.

The strong increase was in line with high CVnCoV development costs throughout 2021. These were mainly driven by high R&D expenses, as well as increased general and administrative expenses and cost of sales, the latter resulting from CVnCoV manufacturing activities including the termination of several CMO contracts within our European manufacturing network.

The overall increase in expenses was partially offset by a strong increase in other operating income based on our grant from the German Federal Ministry of Education and Research.

Financial results for the third quarter decreased by 0.4 million euros to 0.4 million euros and increased by 8.2 million euros to 1.2 million euros over the first nine months of 2021. Net loss was based on negative interest on cash, held in liquid funds to support development and manufacturing activities of CVnCoV and CV2CoV. It was almost fully offset by foreign exchange gains. Pre-tax losses were 143.5 million euros in the third quarter and 407.9 million euros for the first nine months of 2021.

With this, I would like to hand back to Franz for today’s key takeaway messages.

FRANZ Thank you, Pierre. Let me quickly summarize the key messages from today's presentation.

- CureVac remains fully committed to the global fight against COVID-19. We will now focus our priorities and resources with the goal of delivering advanced second-generation vaccines together with GSK, addressing global pandemic and post-pandemic healthcare needs.

- Between the two companies, priorities for our broad infectious disease program are fully aligned to accelerate the development of a future pipeline of mRNA vaccines, including COVID-19, supported by a large number of dedicated experts on both sides.

- Being dedicated to this common goal, we will take an unrestricted technology approach to advance our entire platform and ensure data-driven selection of the best candidate. Highly relevant preclinical data of second-generation candidate, CV2CoV, has recently shown the potential competitiveness of an unmodified mRNA approach, which will be assessed in parallel to modified mRNA constructs.

- Learnings and infrastructure from our first-generation candidate are expected to be leveraged to accelerate momentum across our entire pipeline and to deliver advanced vaccines and therapeutics in oncology and molecular therapy.

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

SARAH 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.