Third Quarter and First Nine Months Financial Results and Business Updates

Presenters

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SARAH

Good morning, good afternoon and welcome to our conference call. My name is Sarah Fakih and I am the Vice President of Investor Relations at CureVac.

Please let me introduce today’s speakers.

On the call with me are Franz Haas, the Chief Executive Officer of CureVac, Pierre Kemula, our Chief Financial Officer and Mariola Fotin-Mleczek, our Chief Technology Officer.

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, Monday, November 30, 2020.

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

In this presentation, we will provide you with business updates and financial results of the third quarter and the first nine months of 2020.

2020 to date has been very transformative for CureVac. We have significantly grown our business, strengthened our unique technology platform and further matured our diverse clinical pipeline. Let me briefly walk you through selected key highlights of the past months.

From the start of the year, we remained highly focused on the development of our COVID-19 vaccine candidate, CVnCoV, to help stop the spread of this dangerous virus.

Based on recently reported positive interim Phase 1 data, we were able to select a 12 µg dose for our vaccine candidate with an optimal balance between tolerability and induced immunogenicity. A pivotal Phase 2b/3 clinical study is due to begin very shortly.

The potential clinical efficacy of CVnCoV was complemented by a best-in-class temperature stability profile, which enables a shelf life of at least three months at standard fridge temperature, which we believe will enable distribution and application of CVnCoV along existing and well-established vaccine cold-chain infrastructures, if it is shown to be effective.

To make our vaccine candidate as broadly available as possible, we were particularly happy to have finalized an Advanced Purchase Agreement with the European Commission to deliver 225 million doses of CVnCoV with an option for an additional 180 million doses.
To meet this demand and create further capacity, we are extending our inhouse manufacturing capacities with an integrated manufacturing network that we are currently establishing across several European countries. We estimate this will provide us with an annual output of up to 300 million doses in 2021 and up to 600 million doses in 2022.

Moving into 2021, we remain focused on continuing to grow the company by successfully bringing CVnCoV to market but also by advancing our broad clinical pipeline.

At the end of September 2020, we had a cash position of 892 million Euros and Pierre will talk about the key financials later in this presentation.

On slide 5, you can see our diverse pipeline, which builds on our differentiated technology platform and focuses on three therapeutic areas:

- prophylactic vaccines for infectious diseases,
- oncology, and
- protein therapies.

The COVID-19 vaccine candidate, CVnCoV, leads our prophylactic vaccine pipeline. Another important part of our infectious disease vaccine portfolio is being developed in collaboration with GSK and the Bill and Melinda Gates Foundation.

The GSK partnership is based on a strategic mRNA technology collaboration, which we entered into in July 2020 and which covers a certain number of mRNA-based vaccines and monoclonal antibodies targeting infectious disease pathogens.
In oncology, our lead candidate is CV8102, a strong immuno-modulator, for which we recently reported updated Phase 1 data at the Society for Immunotherapy of Cancer, or SITC, conference and which I will describe later in greater detail.

In protein therapy, in addition to collaborating with CRISPR Therapeutics and Genmab, we also have collaborations with Yale and Harvard Universities for lung respiratory diseases and ocular diseases. For these programs, we are also developing our proprietary polymer based formulation technology.

On slide 6, let me briefly remind you of our unique technological approach, which is based on the use of natural and non-chemically modified messenger RNA, or mRNA.

We have built extensive expertise and knowhow over the past 20 years in targeted optimization of mRNA, which allow us to tailor the protein coding region as well as the untranslated regions of our un-modified constructs.

A key optimization is the improvement of ribosome interaction, which delivers highly efficient protein production and forms the core of our ability to induce mRNA activity at very low doses.

Our other key optimization process improves the immunogenicity of our mRNA constructs. This is based on a differentiated mechanism of action, mediated through the induction of interferon type 1.

Through this differentiated mechanism of action we believe our COVID-19 vaccine candidate is able to induce broad and balanced immune activation, including both humoral and cellular immune responses that mimic the natural immune response to a COVID-19 infection.
On slide 7, you can see a condensed overview of the most important CVnCoV development milestones that we achieved over the course of this year.

On November 10, 2020, we reported positive interim data from the Phase 1 study initiated in June this year, following selection of a pre-clinically successful vaccine candidate earlier in 2020. Since March, we ramped up GMP manufacturing for CVnCoV at our inhouse GMPIII suite and are now establishing an integrated European network with experienced partners to further expand capacity for the current and planned clinical CVnCoV trials as well as potential market supply.

In September 2020, we started a clinical Phase 2a study in Peru and Panama to confirm safety and evaluate reactogenicity of CVnCoV in adults older than 60 years and in a geographical environment with a high incidence of COVID-19 infection.

As I have already highlighted, we expect to initiate a pivotal Phase 2b/3 in the fourth quarter of 2020, pending the receipt of necessary regulatory approval.

Moving on to slide 8, I would like to give you a brief overview of the recent interim data readout of our comprehensive CVnCoV Phase 1 trial.

The ongoing study assesses the safety, reactogenicity and immunogenicity of our COVID-19 vaccine candidate across a tested dose range of 2 to 12µg. At the time of the interim data read-out, the study had enrolled more than 250 participants.
The Phase 1 data showed that immune responses induced by CVnCoV were comparable to those of recovered COVID-19 patients, thereby mimicking the natural immune response to SARS-CoV-2.

CVnCoV was generally well tolerated and demonstrated activity across all tested doses. We were particularly pleased that at 12µg, binding as well as neutralizing antibody titers reached the level of our human convalescent sera panel. This panel represents a stringent comparison group of high clinical relevance with 67 individuals, who were symptomatic for COVID-19, exhibiting multiple symptoms and of which 24% were hospitalized.

Based on this data, we selected the 12 µg dose to advance into the upcoming pivotal Phase 2b/3 study. This dose currently represents the lowest mRNA dose of any mRNA-based vaccine in an advanced clinical trial.

The Phase 1 study is ongoing and we were recently given approval by the Data Safety Monitoring Board to also escalate to a 16 and 20µg dose to further assess the therapeutic window of CVnCoV.

I am now on slide 9 to give you an overview of the ongoing temperature stability study for CVnCoV, which complements the promising clinical data.

We were able to show that CVnCoV remained stable for at least three months when stored at standard fridge temperature of 5 degrees celsius or 41 degrees Fahrenheit and up to 24 hours as the ready-to-use vaccine when stored at room temperature.
This represents a best-in-class stability profile among the currently developed mRNA-based vaccines.

This is important as temperature stability has emerged as a key characteristic for the logistics associated with the upcoming large-scale COVID-19 vaccination programs, including international delivery of the vaccine, its storage, distribution and individual application.

Let me talk about these multi-stage logistics and associated challenges in more detail on the next slide.

I am now on slide 10 to provide information on the anticipated supply chain for CVnCoV.

Once the vaccine leaves our storage facility, the best-in-class stability profile of CVnCoV is generally expected to allow for international delivery, in-country storage and subsequent distribution of CVnCoV at a standard fridge temperature without the need to re-engineer logistic routes to accommodate ultra-cold temperature devices.

This not only has the potential to facilitate the logistics around the storage and execution of large-scale vaccinations but would also to have a very positive impact on cost and potential waste compared to ultra-low cold chain requirements.

On slide 11, I would like to highlight the recently announced build-up of a broad and integrated European network, which we believe would accelerate the expansion of our current manufacturing capacity to deliver pandemic scale volumes of CVnCoV.
This network includes highly experienced and established partners for each of the key manufacturing steps for CVnCoV. At the core of the network is the cloning of the efficient – and output-optimized – processes we have established in 2020 for CVnCoV in our GMP III manufacturing suite.

In view of upcoming large-scale vaccination programs, we believe this highly coordinated network is expected to mitigate supply chain risks. We believe that it further provides us with the flexibility to respond to changes in demand by easily adding or closing production lines. The network is expected to provide an annual output of up to 300 million doses of CVnCoV in 2021 and up to 600 million doses in 2022.

I am now on slide 12 to update you on the finalization of our Advanced Purchase Agreement with the European Commission for the delivery of 225 million doses of CVnCoV with an option for an additional 180 million doses.

Two weeks ago, the European Commission announced that CureVac had become the fifth company to contribute to this portfolio, once CVnCoV is shown to be safe and effective.

As a results of the signing of the agreement, we will receive a undisclosed upfront payment, which is expected to support the advanced clinical development of CVnCoV and the accelerated ramp up of our CVnCoV manufacturing capacities.

Our lead oncology candidate, CV8102, is currently in a Phase 1 clinical trial for the treatment of solid tumors.
On slide 13, let me give you a short overview of the latest Phase 1 data update we recently reported at the SITC conference.

To briefly remind you, CV8102 is a strong immuno-modulator, which is injected intratumorally. This local immune activation is translated into a systemic reaction that can broadly activate the immune system to reject the tumor.

In the Phase 1 study, tolerability as well as activity of CV8102 is assessed as a single agent, and in combination with systemic anti-PD-1 antibodies in four types of solid tumors.

In the single agent cohort, we previously observed objective tumor responses in two melanoma patients, and stable disease in two additional patients, including shrinkage of non-injected lesions. In the latest update, a new partial response was observed in a patient with cutaneous squamous cell carcinoma, expanding activity from melanoma into a second indication.

In the PD-1 combination cohort, the first response was observed in a PD-1 refractory melanoma patient exhibiting regression of non-injected lesions in the lung and liver.

Intratumoral injection was observed to be tolerated without dose limiting toxicities, at dose levels up to 600 µg. Based on interim data from the ongoing Phase 1 trial, further clinical development of CV8102 will continue after selection of a recommended Phase 2 dose.

With this let me conclude the business update and hand over to Pierre to provide you with key financials for the third quarter and first nine months of 2020.
Pierre

Thank you Franz.

We are executing our financial strategy and as a result have considerably changed the financial profile of the company in 2020.

Our cash position has significantly benefitted from the capital we were able to raise through a private investment round in July 2020, which provided us with a 300 million Euro equity investment of the German government, a 150 million Euro equity investment by GSK, as well as an 110 million Euros of additional, cumulative investments.

A 120 million Euro upfront payment from GSK as part of the collaboration further grew our cash position.

Together with the net proceeds from our successful Nasdaq IPO, amounting to about 193 million Euros, we closed the third quarter of 2020 with a very favorable cash position of 892 million Euros as of September 30, 2020.

This cash position was further supported in July 2020 by a loan agreement with the European Investment Bank for 75 million Euros to support the development of CVnCoV and the build-up of our inhouse industrial-scale manufacturing suites GMP IV. The amount is paid out in three 25 million Euro tranches and we are currently calling tranche 1 and 2. Finally, we have secured a grant by the German Federal Ministry of Education and Research for up to 252 million Euros to support the development and manufacturing of CVnCoV.

Looking at our Profit and Loss statement on the next slide, our revenues for the third quarter of 2020 increased 4.1 million Euros to 5.2 million Euros compared to the same period in 2019. This increase comes mainly from the 120 million Euro collaboration upfront payment by GSK, and the
start of the release of Deferred Revenue into our top line. From this Deferred Revenue, 3.7 million Euros were recognized as revenues for Q3 2020.

For the first nine months of 2020, revenues increased 32.2 million Euros to 42.8 million Euros compared to the same period in 2019. This increase was mainly driven by a one-off event, which was the termination of the Eli Lilly partnership in June 2020. As a result, we recognized the full-deferred revenue amount, or 33.1 million Euros, in our topline.

Cost of sale decreased 11.8 million Euros, or 63% over the first nine months of 2020 driven by lower product costs as a result of the termination of the Agreement with Lilly and lower set-up and quality assurance activities for the production processes.

In line with our strong CVnCoV development efforts initiated at the beginning of 2020 and carried through this year, our R&D expenses, including CVnCoV research material manufacturing expenses, have significantly increased.

R&D expenses increased from 5.4 million Euros in Q3 2019 to 34.6 million Euros in the third quarter of 2020.

For the first nine months research and development, costs more than doubled from 30.7 million Euros in 2019 to 76.3 million Euros in 2020.

Operating loss was 36.8 million Euros for the third quarter of 2020, representing a 92% increase compared to the third quarter of 2019.
For the first nine months of 2020, we posted an operating loss of 63.2 million Euros, an improvement of 2% compared to the same period in 2019, mainly reflecting the full recognition of the Eli Lilly upfront payment in our revenues.

Finance results over the first nine months of 2020 decreased 9.6 million Euros, mainly related to interest incurred on convertible loans, which were fully repaid prior to the IPO.

In the first nine months of 2020, we had a net loss of 71.0 million Euros, or loss of 61 cents per share, compared to a net loss of 63.9 million Euros, or loss of 66 cents per share for the same period in 2019.

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

FRANZ Thank you Pierre.
Let me quickly summarize before we move into the Question and Answer session.

For our COVID-19 vaccine, CVnCoV, we have reported positive interim Phase 1 data and achieved our goal to identify an optimal dose of 12 µg to advance in a pivotal Phase 2b/3.

Analytical testing, complementing the clinical data, revealed a best-in-class temperature stability profile, which will potentially enable us to utilize established vaccine cold chain distribution routes.
To serve the urgent demand for a safe and efficient vaccine we are ramping up significantly our manufacturing capacities – inhouse as well as through a European partner network of experienced and established manufacturing experts.

This capacity is expected to also cover the Advanced Purchase Agreement with the European Commission.

The development of our technology, pipeline and business operations are ongoing and our balance sheet with a cash position of 892 million Euros is expected to give us a solid foundation to execute and deliver on our plans.

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