#	Question	Answer
Production Capacities		
1a	*Overall Capacity*: Could you please give us a broad overview of how much capacity your company has overall for the production of vaccines (in doses or overall) in the different production sites?	
1b	*Overall Capacity*: Is the company willing to lend its expertise/facilities to other developers?	
1c	*Overall Capacity*: How much is being produced in Europe?	
2	*Ramping up*: If you foresee the ramping up of capacity over time, could you please give us an indication of production capacity over time (in doses)?	

#	Question	Answer
3	*Expansion*: If you envisage to expand your capacity for the production of the Vaccine, could you please indicate how much capacity you envisage to have available after the expansion, how long such an expansion will take, where it would be located and how much investment will be needed?	
Agreements for the Production		
4a	With which companies have you got agreements in place to jointly produce vaccines?	
4b	Which of these products would be available for the European market and have a MA for the EU?	
5	In the call, you mentioned that, in addition to using your own capacity, you aim at entering into contracts with CMOs to enlarge the production of the adjuvant and the filling, etc. Please indicate how much capacity from CMOs you are aiming at, with which CMOs you are in discussions, in particular if their envisaged production facility would be located in the EU/in Europe, and where the production capacity would be located.	
6	In the call, you mentioned that you would need to enter into specific contractual structures with CMOs, in particular take-or-pay contracts, in order to reserve capacity in advance. Could you please explain how such contracts are typically structured, how the steps of the payments normally take place (in particular how much is typically	

#	Question	A
	payed in advance) and whether the reserved capacity could also be used for different purposes if the vaccine cooperation with Sanofi should not be successful for the protection against the COVID-19 virus?	• [redacted] • [redacted]
7a	Could you please describe in more detail – compared to your presentation – how you envisage the cooperation with Sanofi, as producer of the antigens?	• [redacted] • [redacted] • [redacted] • [redacted] • [redacted]
7b	Have you already entered into a cooperation agreement with Sanofi, setting out the cooperation more specifically?	• [redacted]
8	In the call, you mentioned that the combination of the antigens and the adjuvant could take place at the bedside, while Sanofi would hold the overall marketing authorisation. How would it be ensured that the right combination would be available for the individuals, would the distribution be taken over by Sanofi?	• [redacted] • [redacted] • [redacted] • [redacted]
Filling and further Steps for the Finalisation of the Production		
9	Could you please describe the further steps following the production of the adjuvant for making it available for distribution (e.g., filling, labelling, etc.)?	• [redacted]
10	We understand that there may be bottlenecks for certain input for making vaccines in huge volumes available (e.g., glass for the filling of the vaccines/adjuvants). Could you please indicate whether you see any such bottlenecks and explain how they could be overcome?	• [redacted] • [redacted]
Marketing and Distribution		

#	Question	Answer
11a	*Distribution*: Have you got marketing and distribution arrangements in place for your product? (EU? Member States? ROW?)	
11b	Will the adjuvants and the antigen be delivered separately or in one package (multi-vials)? (EU? Member States? ROW?)	
11c	Does your product need to be stored and distributed within a cold chain?	
12	Do you envisage to distribute your product via your own distribution network or via third parties with whom you have entered in distribution agreements?	
Administration of the Vaccine		
13a	Do you already now have any insights on the dosage of your product which will be needed per person to grant lasting immunity?	
13b	Do you need specific devices to facilitate delivery? If so, will it be available at sufficient quantities? How will this impact costs?	
14	Could you please update us on the latest measures taken to address concerns related to narcolepsy?	
Cooperation Agreements		
15	Which kind of cooperations/agreements with other players in the industry would you foresee in relation to the Vaccine (apart from production agreements)?	
16	Have you got agreements with governments, governmental agencies or international	

#	Question	Answer
	organisations in place for your product?	•
17	Do you receive financing via these agreements for the outstanding steps up to the production of your product?	• • •
18	Do these agreements include an envisaged allocation of your product?	•
Documents		
19	Could you please share with us any other documents detailing the financing needs for the development and the production of your product (e.g. reports of financing documents prepared for bank financing)?	•
20	Have you got a presentation/ documents showing past experiences with the upscaling of development and production of adjuvants including the time-line and the costs entailed by with regard to the steps for?	•
Financing		
21	What is the amount of at-risk financing already committed to the vaccine project under discussion?	• • •
22a	What parts of that project's at-risk financing have been provided by the company itself and what by other sources and partners?	•

#	Question	Answer
22b	What claims have those partners acquired in return for that financing?	•
23	What are your additional financing needs in order to scale up production to the expected level (please clarify and explain that level in terms of doses and the associated financing needs)?	•
24	From our previous discussion Do you have any further financing needs for production in addition where EU support could benefit the company's program?	• •
25	For the APA, could you please explain the precise financing structure (payment schedule, amounts and what those amounts will be used for at that given time, milestones and dependencies for unlocking further payments, delivery agreements, quantities, etc.)?	•
26	While we understand that whatever benefit you are going to make from this vaccine will be reinvested in vaccine production, please explain a bit more in detail how you are planning to do the pricing of your product and what that implies in terms of returns to be reinvested?	• • •
27	In view of the risk sharing provided through that financing, how do you envisage the sharing of rewards with the EU (discount on pricing? Other?)?	•
28a	What options do you see to share the risk of failure? What options do you see to reuse the acquired capacities / resources for alternative products that could be used to amortise the investment / expenditure?	•

#	Question	Answer
28b	Could those alternative products be supplied to the EU – provided that the EU might be interested?	•
Liability		
29a	Would you expect your liability to be limited?	•
29b	If so, under which circumstances and how?	•
		•
		•
Regulatory Flexibility		
30a	Do you see any need to facilitate the regulatory process for bringing the Vaccine successfully to the market as soon as possible, provided that safety and efficacy are demonstrated?	•
30b	What are the specific regulatory difficulties that you envisage?	•
		•
		•
Looking to the Future		
31	Can the technology you are using be standardized to making it particularly suitable for rapid	•

#	Question	Answer
	response to emerging infectious diseases?	
32	What are the key lessons learned from the COVID19 outbreak which in your view are particularly relevant for the future crisis preparedness?	
33a		
33b	What types of vaccine platforms are you planning to cover? How quickly will you be able to switch between platforms? What capacity in terms of doses are you envisaging?	
33c	What costs are you expecting?	