Federico Goodsaid – CEO, MBQ Pharma, Puerto Rico

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Dr Federico Goodsaid, CEO of Puerto Rico's first biopharmaceutical start-up MBQ Pharma, has previously worked at Vertex Pharmaceuticals and TOMA Biosciences and is considered an expert in regulatory affairs. Here, he highlights the encouraging results MBQ Pharma has achieved in preclinical efficacy and safety trials and acknowledges the backing the start-up has received from the Puerto Rican life sciences community.

Dr Goodsaid, you have had a long career in the pharma industry working at Big Pharmas like Abbott and Schering-Plough as well as biotechs like Vertex on the US mainland. What motivated you return to Puerto Rico and take the position as the CEO of MBQ in PR?

I returned to Puerto Rico because I see high potential and impact in this project. For the first time in the history of the island, we have the opportunity to take intellectual property from a university and use it for potential commercialization. Academic institutions outside the US mainland struggle to transform basic research into intellectual property. This also applies to the University of Puerto Rico (UPR). The Puerto Rico Science, Technology and Research Trust (PRSTRT) has gone great lengths in developing the structures required for the development of intellectual property for the growth of start-ups like MBQ Pharma. They made an agreement with the UPR to overcome the existing barriers of the patenting process at the university. By the time I came here, the patents for the structural platforms, and for our lead candidate MBQ167, were already issued. Additionally, the

PRSTRT has done a great job of bringing people from academia, industry and the government together to establish a life sciences ecosystem on the island, extending beyond manufacturing and opening new avenues of collaboration.

MBQ Pharma has received a lot of media attention when being founded in late 2018 as it is the first Puerto Rican biopharma company. Could you please introduce the company to our international readers?

MBQ Pharma is the first startup biotech company in Puerto Rico lead by scientists from the UPR system. It is currently in preclinical safety and efficacy testing for MBQ 167, a metastasis blocking molecule developed at UPR, and for which MBQ Pharma has an exclusive license for the development and regulatory approval. We are supported by different stakeholders in the Puerto Rican investment and life science communities, who have invested in the preclinical development stage of MBQ-167. The MBQ Pharma intellectual property was invented by Drs. Suranganie Dharmawardhane, Linette Castillo Pichardo, Cornelis Vlaar, and Eliud Hernández O'Farrill from the Medical Sciences Campus of the UPR. MBQ Pharma has been made possible by the support of Dr. Jose F. Rodriguez-Orengo who brought together academic, government and private stakeholders to share the work and risk required to develop this company in Puerto Rico. Also linked in this effort are the Susan G. Komen Foundation and FDI Clinical Research. The immediate goal of MBQ Pharma is to reach the acceptance by the FDA of its IND data package and clinical protocol proposal supporting first-in-human studies for MBQ-167.

What have been the first steps so far?

We started our operations in February 2018. We met our first investors in May, and PRIDCO agreed to support us with 100,000 USD as part of the "Pymes Innovadoras" program. We met physicians who worked with UPR in the past, and we considered them as potential investors, as we received very positive feedback from them. We presented the preclinical data, which shows excellent efficacy in rats to block cancer metastasis at 1mg/kg, and received an investment of for 250,000USD without any further questions at our first meeting. Not a standard investor rationale, but it shows the commitment of these investors to drive Puerto Rico forward, as an R&D hub. Cold investment reasoning does not explain the investments of our initial 6 investors. A belief in the extraordinary team that we have and what Puerto Rico can do does.

Considering backing has been received due to the great results for efficacy, what findings have been made on the safety profile of the drug candidate so far?

We had initially a lot of data on the efficacy side but not much on safety site, so we contracted Charles River laboratories to gather data around drug safety. Toxicologists at Charles River laboratories pushed the doses of MBQ-167 from 1mg/kg up to 2g/kg, with no negative observations, and normal clinical signs, weight gain and pathology report. This result accelerates our development timelines, as to reach an IND package. We will have an abbreviated non-GLP study in dogs and will meet with FDA earlier than planned to share the non-GLP package we have for safety and the efficacy studies as well as the clinical protocol proposal for the first-in-human studies. We aim to hold first-in-human trials in Puerto Rico. Oncologist Dr. Mirelis Acosta, CMO at FDI Clinical Research and MBQ Pharma, and Dr Fernando Cabanillas, head of oncology at the Auxilio Mutuo Hospital and MBQ Pharma board member will lead the clinical study design.

INDUNIV's Ivan Lugo highlighted that the infrastructure for small businesses and start-ups, especially in the pharma industry, needs to be improved as Puerto Rico is only ranked 41st on the Global Entrepreneurship Index. As one of the few start-ups in the medical ecosystem in PR, what are some of the main challenges you are facing?

It is clear that there is no history of venture capital investment in Puerto Rico biopharma, so this is a challenge for start-ups. We decided to start with a pro-bono business approach, to keep expenses as low as possible. PRIDCO has supported us financially as we designated MBQ Pharma as an Act 73 company. However, in order to take advantage of tax benefits in Act 73, we need to maximize our R&D expenses in Puerto Rico. This is not always possible, as we found out with the nonclinical safety studies and process development for manufacturing kg lots of MBQ-167. A major challenge for MBQ Pharma will be to actually help develop potential R&D partners in Puerto Rico for pre-clinical studies and small manufacturing processes. However, we have an excellent infrastructure in life-science research at the UPR system and the newly created Molecular Sciences Center, where state of the art equipment is available.

What is your partnership strategy entering the next stages of product development and your vision for MBQ Pharma?

The pre-IND meeting is critical for MBQ Pharma, as it will help us to mitigate the regulatory risk for any potential investors, which help us for our GLP and even our phase 1 studies. We have the safety and efficacy data we deem adequate for justifying a meeting at such an early stage. Currently, it is difficult for us to plan beyond phase 1, but we have ambitious goals for the next five years. We plan to reach the phase 1 study milestone, which requires a relatively modest amount of investment and we have the facilities and infrastructure through FDI Clinical Research to perform such studies. Going past phase 1 is a different story, as it would require a large investment, so our primary goal is to pass the first phase of clinical trials for now.

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