Laszlo Dinca – Managing Director, Vanessa Research, Hungary

It is paramount that a sustainable internationalization strategy is devised and implemented if Vanessa Research is to help patients suffering from MVID

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Laszlo Dinca, managing director of Vanessa Research - Hungary, shares his insights on the company's rare and orphan disease portfolio; the intentions behind the acquisition of Hungaro-Gal Pharmaceutical Manufacturing [HG Biotech]; Hungary as a development market for biotechnology companies; and the future objectives of the company.

Can you introduce yourself and Vanessa Research (VR)?

Vanessa Research was founded in late 2015 with the idea and hope of finding an alternative treatment for a lethal, rare, paediatric disease called Microvillus Inclusion Disease [MVID].

The company was founded by Dr Dmitry Kravtsov and Prof. Norman Gray to translate their bench science work into a commercially available product.

Currently, the company has four divisions (Pharmaceutical R&D, Medical, Pharmaceutical Manufacturing, and Consumer and Public Health).

Diarrhoeal disease research and development is the company's core competency and primary focus area. The flagship product is branded Shylicine™, a cocktail drug candidate for treating MVID. A second product is HunaZine™, a cholera treatment currently in preclinical development.

The company first started its operation at the *Centre for Innovation and Entrepreneurship* at Quinnipiac University in Hamden, Connecticut. In 2016, they moved from the University's pre-incubator to their current location, also in Hamden.

The early years of the company were dedicated to basic translational research.

By 2017, the company had a Phase 1 product, Shylicine™, for safety and efficacy testing. In 2018, further advances led to the development of the cholera drug, HunaZine™. After four years, VR has become a world authority in anti-diarrhoeal diseases.

The goal and mission of the company reside in our motto: "giving hope where none existed." The company has made its mark by focusing on diarrhoeal diseases which have an extremely high rate of mortality but are often overlooked because they fall into the "rare" or "less profitable" category.

What is MVID and what is the scale of this unmet medical need?

MVID is a genetic disease of new-born babies and young children that affects the growth and function of the entire intestine, leaving patients unable to absorb nutrients and causing severe untreatable diarrhoea. It is classified as a rare disease because there are less than 300 registered cases and only seven centres in the world that can definitively confirm the diagnosis.

MVID has been found to be more prevalent in infants of Middle Eastern, Western European, and Navaho descent. Thus, there is a need for the global availability of Shylicine™.

How does Shylicine™ differ from current treatment methods?

The only way that MVID has been treated until now is by sustaining the patient's life for as long as possible by providing nutrition and hydration intravenously via total parenteral nutrition (TPN) – a highly-invasive treatment associated with poor quality of life. MVID is a fatal disease; with an enormous volume of diarrhoea resulting in rapid dehydration and malnutrition, sepsis, and liver failure being the primary known causes of death in patients. The latter two are complications of the TPN treatment.

The goal of Shylicine™ is to reverse intestinal abnormalities caused by MVID, allowing the intestine to absorb essential nutrients and fluids as a healthy intestine would. Shylicine™ is an oral treatment, meaning that patients may no longer require nearly continuous IV feeding and will be

able to live without TPN.

What is the anticipated development pipeline of Shylicine™?

Completing clinical trials and obtaining market authorization is a lengthy process, although working on a rare disease or orphan drug does help to speed up the course. However, the longer the medicine is not on the market, the more children will succumb to MVID.

Shylicine™ is on the Orphan Drug track, and its Phase II clinical trial has begun in July 2019 in Turkey. Data obtained in the trials will be used for marketing authorizations in the European Union and Turkey, followed by the US.

What is the strategic significance of Hungary for Vanessa Research?

Hungary is of major strategic significance to VR. The relationship began with Hungarian Quinnipiac University and Fulbright scholars and has matured into a resource for talent and competitive manufacturing capabilities.

In the specific case of our recent HG Biotech acquisition, Hungary has a long and strong tradition with pharmaceuticals and its status as a member of the EU along with the presence of a strong research network. This acquisition will facilitate VR’s access to the European market once the drug is authorized. The National Institute of Pharmacy and Nutrition (OGYÉI) is a part of the European medicines regulatory network, which works closely with the European Medicines Agency (EMA) on the regulation of medicines in the EU. All the above played an important role in VR deciding to establish a foothold in Hungary.

What was the strategic intention behind the acquisition of HG Biotech?

In late 2017, the research and development team started experimenting with alternative formulations using the active pharmaceutical ingredient in Shylicine™ to potentially serve as treatments for other diarrhoeal diseases. The result was a formulation that neutralizes the diarrhoea caused by the cholera toxin.

We patented this product, HunaZine™, in early 2018. This created new horizons, as cholera is still an enormous issue in developing countries with millions of cases and roughly 100,000 deaths each

year. VR previously had no manufacturing division of its own, hence the decision was made to acquire manufacturing capabilities in order to control and ensure the supply and the quality of our medicine. This brought about our newly formed division: pharmaceutical manufacturing.

The new division is under the guidance of Bence Krümmer, Managing Director of HG Biotech. Thanks to Bence's expertise and efforts, our team has grown, and the capabilities of Vanessa Research have been expanded significantly. Not only is the long-term vision of bringing our medicines to patients around the world one step closer, but we now also have the ability to offer pharmaceutical contract manufacturing services to other pharma companies seeking the level of quality that we require for our own products.

What are the manufacturing capabilities and service offerings that HG Biotech can provide its clients?

HG Biotech has the capacity to offer end-to-end, full-scale contract manufacturing services – "from raw material sourcing to the pharmacy shelf."

We are able to produce drug, nutritional, and cosmetic products in a wide variety of solid, liquid, and topical dosage forms; we offer a portfolio of registered fixed-formulation drugs; we have a dedicated facility for the manufacturing of β-lactam antibiotics…and this is just the beginning. We also have in-house experts performing analytical services, full capability to produce primary and secondary packaging, warehousing and serialization services, and more.

What competitive advantages make HG Biotech a partner of choice when it comes to CMO services?

Basically, the capacity and capabilities that we have are unparalleled for a mid-sized CMO (contract manufacturing organization). Many pharma companies struggle to find a CMO with the ability and willingness to run-off the smaller batch sizes needed for an investigational product, or even just to meet the demands of a product in a defined market space (say, Hungary or Eastern Europe) that may seem comparatively modest to a pharma giant with a well-established international presence. Our business model puts us in the ideal position to accommodate smaller batches at a very competitive price – and produced with the same level of quality and attention to detail that we expect for our own drugs.

How would you assess the Hungarian landscape as a development market for a biotechnology company?

In the last few decades, though the pharmaceutical industry expanded, there wasn't anything that disrupted the industry. However, in the last few years there has been a lot of movement in the biotechnology sector and Hungary provides an adequate ecosystem for such new endeavours.

The government welcomes and supports such efforts: it benefits from one of the highest investment flows in Europe. There is a highly skilled and highly educated workforce present, and a mix of international and local companies, which creates an ideal competitive environment. The economic and political agenda aims to position the country in such a way that it is associated with "invented in Hungary" rather than "made in Hungary". This ties well with the ambition of VR, aligning with our long-term vision of having Hungary as primary centre for pharma invention and development.

How does Vanessa Research raise its profile and build collaborations with industry players?

Over the past few years, we have been deeply focused on building our collaborative network with the ultimate goal of bringing innovation and products to the market for the benefit of our patients. We've found that an effective way to raise our profile has been to network and share our knowledge via innovative medical events. We recently sponsored the 2019 Congress of the European Society for Developmental Perinatal and Paediatric Pharmacology in Basel, where Dr. Kravtsov – our VP of R&D – shared our MVID research findings with the industry. We are also promoting the global awareness of rare diseases by sponsoring and participating in the Rare Disease Day conferences in the US and Europe.

Our company is new to the Hungarian ecosystem and we aspire to be a vivid partner in the pharmaceutical environment, particularly as we expand into the realm of contract manufacturing.

What is the company culture you want to establish in the Hungarian operations?

Our employees are the backbone of the company and are our most valuable assets. Without their efforts and expertise, VR is unable to impact the lives of patients that suffer from rare and orphan

diseases. Hence, it is of utmost importance that every task performed in the company is done with a result-oriented approach. VR is here to save lives and each action influences the success of that outcome: this is the biggest motivation for anyone.

What are your objectives for this affiliate in the next five years?

The main mission is to produce drugs for MVID and cholera. Furthermore, we aim to solidify the strong foundations of the contract manufacturing operations at HG Biotech, and to build upon that. The idea is to bring these drugs to patients as quickly as possible and we believe that in-house manufacturing is the best way forward for us.

Partnerships and good business relationships are at the heart of such endeavours. Hence, VR aims to retain and strengthen relationships with HG Biotech’s current clients while simultaneously working to build new partnerships.

Finally, it is paramount that a sustainable internationalization strategy is devised and implemented if Vanessa Research is to help patients suffering from MVID.

What is your final message on behalf of Vanessa Research?

We are humble and we want to stay that way while creating an added value for our patients, the healthcare industry, and the Hungarian business ecosystem.

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