GÃ¡bor OrbÃ¡n â?? CEO, Gedeon Richter

Our advancement in biotechnology has been a key development for Gedeon Richter this year as we move forward in our transition to become a truly specialty pharmaceutical manufacturer

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GÃ¡bor OrbÃ¡n, CEO of Gedeon Richter, highlights the recent turnaround of the companyâ??s performance, its exciting new collaboration with Allergan in the US market, and the landmark launch of Gedeonâ??s first company-developed biosimilar in Japan.

GÃ¡bor, shortly after you took over as CEO in 2017, unexpected challenges surfaced and put Gedeon Richter in a tough position. What hurdles have you faced in the role and on the other hand what do you see as the shining light at the end of the tunnel for Richter?

Taking on the role of CEO was a trial by fire. 2017 was the year that everything played out as we had planned with strong share price performance and our product, ESYMA, for the symptomatic treatment of uterine fibroids delivering strong results. Additionally, our underlying business was performing well, exchange rates were recovering in our favour, and it was the first full year we earned royalties from our partner Allergan for the product cariprazine (VRAYLAR in the US) as well.

However, due to the adverse reports for ESMYA in Europe, the restrictions put on the label and the requirement of regular liver function monitoring has limited the potential of the product. At the same time, we have seen headwinds in our legacy business â?? off-patent products mostly sold in the traditional markets of Hungary, being the CIS and CEE regions. These challenges have come in the form of price erosions and loss of productivity resulting from the EU serialization obligation that entered into force in February. However, the implementation of serialization is a technical issue that

has since been resolved within the past quarters.

On the positive side, we have seen a strong pick up in marketing activities and sales of cariprazine in Europe and especially the US. Furthermore, we have secured several licensing agreements with trusted partners around the world to ensure access to this product to patients globally. In particular, VRAYLAR in the US has seen tremendous success and it continues to be the fastest-growing antipsychotic drug in the market even three years after its initial launch. We are also continuing to add new indications to the label to broaden its commercial potential very significantly.

What is the uniqueness of cariprazine and how is it differentiated from existing therapies on the market?

We initially launched cariprazine with two indications in the US: schizophrenia and bipolar mania. A third indication was added to the productâ??s label on May 23 and launched in June for expanded use to treat depressive episodes associated with bipolar I disorder. Thanks to the marketing efforts of Allergan in the US we have witnessed a significant increase in prescription and we are all very pleased with the results.

Adding these indications were, of course, important for broadening its scope of prescription, but also equally as crucial for establishing cariprazine as a spectrum product for a disease that has such a nature. There are many overlaps in the symptoms of bipolar and schizophrenic disorders and it is challenging to make a diagnosis for patients. Therefore, the more coverage a product has, the more assurance we can deliver to patients and health care professionals.

For this reason, the available generic products fall short and there remains an unmet need for an original product like cariprazine in a space which may seem saturated at first glance. This product has a competitive edge thanks to its efficacy in tackling the negative symptoms of schizophrenia, in particular, lethargy which is closely related to the disease and its treatment. Furthermore, cariprazine has a stronger side effect profile compared to existing alternatives on the market. At this moment, the Bloomberg analyst consensus for VRAYLAR is to pass the billion-dollar mark in the US next year, which would officially make the product a blockbuster drug.

VRAYLAR in the US is poised to take increasing importance for Gedeon Richter, do you see the possibility of maybe opening a full operation in the market?

At the moment we are very pleased with the agreement we have with Allergan. Despite the upcoming acquisition of the company by Abbvie, VRAYLAR is still positioned to be a star product of the combined entity and we expect the product to be given the appropriate resources to ensure continued success.

What were the other key events that marked this year for Gedeon Richter?

Our advancement in biotechnology has been a key development for Gedeon Richter this year as we move forward in our transition to become a truly specialty pharmaceutical manufacturer. Biotechnology products are difficult to develop and launch, so we are quite proud of our success with TERROSA â?? the companyâ??s first self-developed biosimilar. Once the originator went off patent, we were ready to deliver the product across Europe that same day. Even though four months have

passed, TERROSA continues to be the only teriparatide biosimilar for the treatment of osteoporosis in Europe.

TERROSA has also been launched successfully in Japan at the end of November. Our licensing partner Mochida is a company that is very similar to Richter in both size and values with whom we are pleased to be working alongside. We expect similar opportunities in Japan as in Europe given the large osteoporosis market and remarkable uptake of biosimilar products in the country.

In 2018, Richter inaugurated its molecular biology laboratory in the city of Debrecen â?? what is the significance of this HUF 1.7 billion investment for the companyâ??s biotech capabilities?

The microbiology laboratory allows us to conduct R&D activities in the early cell-line phase of development. The innovative projects in our pipeline will be instrumental in filling the capacities we have at the site. In Debrecen, we are currently working diligently to develop Denosumab, a biosimilar in the preclinical stage with both oncology and rheumatology indications both very central to our biotechnology strategy.

It seems that in both licensing and development activities, industry partnerships are an important strategy for Richter. What are the benefits of having a strong collaborative-network approach to business development?

Partnerships are absolutely an essential part of the strategy for midsize players like Richter. Our approach to partnerships is a necessary part of operations because we cannot cover the entire value chain for every product category. CNS is an example where we start with the initial research and develop up until proof of concept, where we then need a partner to help bring the product to certain key markets like the US. We also work with the likes of Mitsubishi Tanabe, Mochida and other midcaps around the world to sell specialty pharma products in markets where Richter does not have a strong presence like MENA for example.

One example of an important partnership for the company is with Recordati to market cariprazine in Western Europe and Algeria, Tunisia, and Turkey under the brand name REAGILA. A few weeks ago, Springer Medizin Verlag, a prestigious German scientific publisher recognized Richter with a drug of the year award. There are four categories and REAGILA was awarded for specialist care.

Another example of our different strategies across the value chain is in our womenâ??s health portfolio where we prefer to in-license or acquire products, such as BEMFOLA in fertility which we acquired in 2016. In womenâ??s health, unlike for our generic and CNS portfolio, we have a worldwide network of sales representatives in Europe, Latin America, Australia, Russia, Asia, but not North America.

Womenâ??s health seems to be quite an important space for Gedeon Richter. How would you define the companyâ??s positioning in this therapeutic area?

In this area, we are looking to build a full portfolio that covers infectious diseases, menopause, contraception, fertility, and endometriosis. After finding assets that we can bring into our portfolio, we have a unique vertically integrated manufacturing capability and strong sales force to market the

products all over the world.

Recently we have made significant progress in bringing in new assets such as the combination oral contraceptive, containing 15 mg estetrol (E4) and 3 mg drospirenone. Unlike third and fourth generation contraceptives that contain ethinyl estradiol, which is often considered to be linked to deep vein thrombosis, our new combination using E4 eliminates this risk. This is a product we are aiming to launch in the market by 2021.

Furthermore, we signed a series of agreements this October with the US-based Mycovia for the commercialization and manufacture of a novel oral antifungal product. While there is still development work to be done, this asset is currently in Phase III clinical trials for the treatment of Recurrent Vulvovaginal Candidiasis (RVVC). This is yet another example that Richter is working consistently to have a full portfolio of womenâ??s health products that address every condition for every age group of patients.

It is no secret that Gedeon Richter is in a transition phase from branded generic pharma towards being a specialty producer. Can you offer an overview of your vision for the future of the company?

Richter has a relatively balanced traditional portfolio and pipeline of branded generic products which are well established and reliable but have limited opportunity for growth. Therefore, we are looking for growth in the specialty area of our business, and in the near term, the main driver aside from cariprazine will be womenâ??s health. The second driver of our specialty transformation, more in the medium term, will be biosimilars. We have launched our first product in this area and while it will take time to reach its peak sales, we are working on additional products to cultivate a balanced pipeline. Third, we are working on innovative CNS projects, an expertise we have built up over many years, to fulfil unmet needs in neuropsychiatric therapies. Due to our size, our ambition cannot be to develop disease-modifying treatments, but symptomatic treatments, which still remain extremely relevant in this area.

What values are you implementing across the organization to accomplish a unified transformation?

Aside from the renewal of our product portfolio, I have to oversee the transformation of the organization as well. There is a strong emphasis on becoming more flexible and agile within the company in addition to focusing on KPIs. While on one hand, our uniqueness comes from our over-one-hundred-year history, at the same time this makes it difficult to shape a new corporate culture that is tailormade to the changing conditions of the modern healthcare market.

Nevertheless, a strength of Richter is our culture of thinking long term. While as a public company we must deliver results to our shareholders each quarter, we are able to create strategies that will ensure Richterâ??s continuous success in the future. The transformations happening today are very exciting and we are heading in a direction to become a leading player in our league.

If you had one phrase to define Gedeon Richter what would it be?

Innovation to improve quality of life.

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